IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS



VERA GROPPER,

Plaintiff,

v.

MERCK & CO., INC., and John and Jane Does, as Sales Representatives for MERCK & CO, INC.,

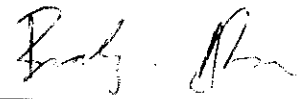
Defendants.

CIVIL ACTION No. 05-10217-WGY

**NOTICE OF FILING CERTIFIED COPIES OF STATE COURT PAPERS**

Pursuant to 28 U.S.C. § 1446, defendant hereby files certified copies of all records and proceedings in the superior court action (Middlesex County Superior Court Civil Action No. 04-4301).

MERCK & CO., INC.
By its attorneys:



James J. Dillon (BBO# 124660)
Bradley E. Abruzzi (BBO# 651516)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110-2600
(617) 832-1000

Dated: February 16, 2005

**CERTIFICATE OF SERVICE**

I certify that a true copy of the foregoing NOTICE OF FILING CERTIFIED COPIES OF STATE COURT PAPERS was served on February 16, 2005 by hand, upon:

David C. Strouss
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
**Counsel for Plaintiff Vera Gropper**

**MICV2004-04301**

**Vera Gropper**

**v.**

**Merck & Co., Inc., et al.**

**Removed to United States District Court**

**Commonwealth of Massachusetts**
**SUPERIOR COURT DEPARTMENT**
**THE TRIAL COURT**
**CAMBRIDGE**

MICV2004-04301

I, Patricia A. McCann, Deputy Assistant Clerk of the Superior Court, within and for said County of Middlesex, do certify that the annexed papers are true copies made by photographic process of pleadings entered in the Superior Court on the 10th day of February, in the year of our Lord, Two Thousand Five.

In testimony whereof, I hereunto set my hand and affix the seal of said Superior Court, at Cambridge, in said County, this 10th day of February, in the year of our Lord, Two Thousand Five.

Patricia A McCann

Deputy Assistant Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VERA GROPPER,

Plaintiff,

v.

MERCK & CO., INC., and John and Jane Does, as Sales Representatives for MERCK & CO, INC.,

Defendants.

CIVIL ACTION No. _____

05 CV 10217 WGY



**NOTICE OF REMOVAL**

Pursuant to 28 U.S.C. § 1446, defendant Merck & Co, Inc. ("Merck") files this Notice of Removal and states:

1. Merck is the single named defendant[1] in an action commenced against it by the plaintiff, Vera Gropper, pending in Middlesex County Superior Court in the Commonwealth of Massachusetts, captioned Vera Gropper v. Merck & Co, Inc., Civil Action No. 04-4301 (the "Superior Court action"). True copies of all process, pleadings and orders served on Merck in the Superior Court action are attached hereto as Exhibit A and specifically incorporated herein.

2. In her Complaint, Plaintiff Vera Gropper alleges that she is a resident of Massachusetts. Defendant Merck is a corporation organized under the laws of the State of New Jersey with a principal place of business at One Merck Drive, Whitehouse Station, New Jersey. There is, therefore, complete diversity of citizenship.

3. The Plaintiff claims compensatory damages for a "Myocardial Infarction," medical expenses, mental and physical pain and suffering, loss of present and future earnings,

[1] The Complaint also lists unnamed Merck sales representatives as "John and Jane Doe" defendants. Federal law provides, however, that "[f]or purposes of removal . . . , the citizenship of defendants sued under fictitious names shall be disregarded." 28 U.S.C. § 1441(a).

and treble damages under Chapter 93A of the Massachusetts General Laws. Accordingly, Merck suggests that the matter in controversy in the state action will exceed the sum or value of $75,000, exclusive of interest and costs.

4. Merck was served with a summons and a copy of plaintiff's Complaint and Demand for Jury Trial on January 14, 2005. Consequently, this notice is timely under 28 U.S.C. § 1446(b).

5. This action is one of which this Court has jurisdiction pursuant to 28 U.S.C. § 1332 and that may be removed to this Court by Merck.

MERCK & CO., INC.
By its attorneys:

James J. Dillon (BBO# 124660)
Bradley E. Abruzzi (BBO# 651516)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110-2600
(617) 832-1000

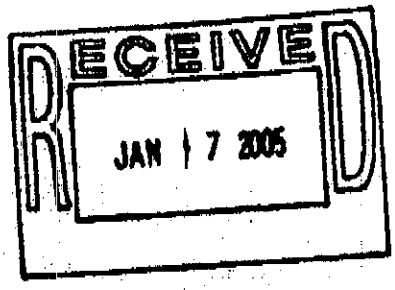
Dated: February 3, 2005

**CERTIFICATE OF SERVICE**

I certify that a true copy of the foregoing NOTICE OF REMOVAL was served on February 3, 2005 by hand, upon:

David C. Strouss
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
**Counsel for Plaintiff Vera Gropper**

CT System




**Service of Process Transmittal Form**
**Boston, Massachusetts**
**01/14/2005**
**Via Federal Express (2nd Day)**

**TO:** Debra A Bollwage Assistant Secretary
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889-0100

**RE:** **PROCESS SERVED IN MASSACHUSETTS**

**FOR** Merck & Co., Inc. Domestic State: NJ

**ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:**

| | |
|---|---|
| **1. TITLE OF ACTION:** | Vera Gropper, Plf vs Merck & Co, Inc et al, Dft |
| **2. DOCUMENT(S) SERVED:** | Summons, Complaint |
| **3. COURT:** | Commonwealth of Massachusetts, Middlesex Superior Court<br>Case Number 04-4301 |
| **4. NATURE OF ACTION:** | Product Liability |
| **5. ON WHOM PROCESS WAS SERVED:** | CT Corporation System, Boston, Massachusetts |
| **6. DATE AND HOUR OF SERVICE:** | By Process server on 01/14/2005 at 12:00 |
| **7. APPEARANCE OR ANSWER DUE:** | Within 20 Days |
| **8. ATTORNEY(S):** | No address given |
| **9. REMARKS:** | |

**SIGNED** CT Corporation System

**PER** Yvette Concepcion /AL

**ADDRESS** 101 Federal Street
Boston, MA 02110
SOP WS 0006919011

Information contained on this transmittal form is recorded for C T Corporation System's record keeping purpose only and to permit quick reference for the recipient. This information does not constitute a legal opinion as to the nature of action, the amount of damages, the answer date, or any information that can be obtained from the documents themselves. The recipient is responsible for interpreting the documents and for taking the appropriate action.

TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED: —
TORT — MOTOR VEHICLE TORT — CONTRACT —
EQUITABLE RELIEF — OTHER

# COMMONWEALTH OF MASSACHUSETTS

SUPERIOR COURT
DEPARTMENT
OF THE
TRIAL COURT
CIVIL ACTION
No. 04-4301

MIDDLESEX, ss
[seal]

Vera Gropper, Plaintiff(s)

v.

Merck & Co., Inc. and John and Jane Does, as Sales Representatives for Merck & Co., Inc., Defendant(s)

## SUMMONS

To the above-named Defendant: Merck & Co., CT corporation, 101 Federal Street, Boston, MA

You are hereby summoned and required to serve upon David C. Strouss, Esquire, Thornton & Naumes, LLP, plaintiff's attorney, whose address is 100 Summer Street, 30th Floor, Boston, MA 02110, an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Cambridge, MA either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Suzanne V. DelVecchio, Esquire, at ..... the 12th day of January, in the year of our Lord 2004

A TRUE COPY: ATTEST

CONSTABLE

Edward J. Sullivan
Clerk

NOTES.
1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all such defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.

NOTICE TO DEFENDANT — You need not appear personally in court to answer the complaint, but if you claim to have a defense, either you or your attorney must serve a copy of your written answer within 20 days as specified herein and also file the original in the Clerk's Office.

CCP/CIVIL SMR — 001

04-4301

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
DEPT. OF THE TRIAL
COURT

VERA GROPPER,
Plaintiff

vs.

MERCK & CO., INC.,
and John and Jane Does, as
Sales representatives for
MERCK & CO., INC.,
Defendants.

COMPLAINT

Now comes the plaintiff, by her attorneys, and files the following complaint:

1. Party Plaintiff

The Plaintiff, Vera Gropper, resides at 14 Hall Avenue, Somerville, Massachusetts, 02144, and at all relevant times herein, was a resident of the Commonwealth of Massachusetts.

2. Party Defendants

2A. The Defendant, Merck & Co., Inc., (hereinafter "Merck") is a corporation incorporated under the laws of the State of New Jersey, having a principal place of business in the State of New Jersey, and has conducted business in the Commonwealth of Massachusetts. At all relevant times, hereto, Merck was in the

business of promoting, marketing, and distributing the pharmaceutical VIOXX(Refecoxib).

2b. John and Jane Does are sales representatives for Merck promoting and distributing VIOXX to physicians within the Commonwealth of Massachusetts. Upon information and belief all or some of the John and Jane Doe Sales Representatives are individuals residing in the Commonwealth of Massachusetts.

As used in this Complaint, the term "defendant" shall include any party defendants identified in paragraphs 2a through 2b hereof, and their predecessors, which shall include, but is not limited to, any person, corporation, company or business entity: which formed part of any combination, consolidation, merger or reorganization from which any party defendant was created or was the surviving corporation; whose assets, stock, property, products or product line was acquired by any party defendant; whose patent rights, trademark rights, trade secrets of goodwill was acquired by any party defendant; or which was dominated or controlled by any party defendant to such an extent that said party defendant was the "alter ego" of said corporation.

**JURISDICTION**

3. The plaintiff's cause of action arises from the defendants' (1) transacting business in Massachusetts; (2) contracting to supply and/or sell goods in Massachusetts; (3) doing or causing

a tortuous act to be done in Massachusetts; and/or (4) causing the consequence of a tortuous act to occur within Massachusetts, and the defendants do, or solicit business, or engage in a persistent course of conduct or derive substantial revenue from the sale of goods in Massachusetts.

**FACTS**

4. At all relevant times herein, the defendants individually and/or in conjunction with other persons or entities for whose conduct they were legally responsible developed, created, manufactured, designed, tested, labeled, packaged, distributed, supplied, marketed, sold, advertised, and/or otherwise distributed in interstate trade and commerce the drug VIOXX.

5. On information and belief, the drugs were manufactured, distributed, and sold as medication to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, for the management of acute pain in adults, and the treatment of primary dysmenorrheal.

6. In May of 1999 VIOXX was approved by the FDA. The defendants individually began actively and aggressively promoting, marketing and selling the drug in the United States and eighty other countries. The defendants fraudulently induced people to use its drug for arthritis and pain relief without adequately warning people of the risks associated with the drug that were known or should have been known to the defendants.

7. The defendants engaged in a nationwide marketing scheme including but not limited to the Commonwealth of Massachusetts and participated in advertisements and promotional enhancements and literature, directly targeting consumers and various physicians and other health care providers.

8. The defendants, engaged in the study "VIOXX GATROINTESTINAL OUTCOMES RESEACH" ("VIGOR"). The results of the study were released in March 2000 and the findings demonstrated that VIOXX patients were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on Naprosyn (Naproxen).

9. On information and believe, MERCK mislead patients and health care providers by using press releases, promotional materials and oral representations made by MERCK and through MERCK's sales representatives, to offer an untested hypothetical explanation to assert that VIOXX did not cause an increase in MIs as demonstrated in the VIGOR study.

10. On September 17, 2001 a warning letter was sent by the Department of Health and Human Services, Food and Drug Administration (FDA), requiring MERCK to end all violative promotional materials and send "dear Healthcare provider" letters to communicate the accurate findings and risks of VIOXX demonstrated in the VIGOR study.

11. The Defendant MERCK did not communicate the findings of cardiovascular risks from the

VIGOR study until April 2002 when they sent a "Dear Doctor" letter and made changes and additions to VIOXX label regarding cardiovascular risks under the header "Precautions". MERK did not add stroke or any of the other adverse reactions linked to VIOXX that it knew or should have known.

12. The defendants engaged in and/or actively participated in inducing and/or encouraging use of VIOXX by providing incentives for its use and by encouraging physicians and other health care providers to prescribe it without the benefit of the full and complete information known to the defendants. The defendants disseminated false and misleading materials which failed to disclose the risks associated with the use of VIOXX.

13. Upon information and belief, the defendants also unfairly and deceptively encouraged the use of VIOXX, by falsely misleading potential users including the plaintiff, Vera Gropper, concerning the risks associated with its use. By affirmative misrepresentations and omission, the defendants sought to create the impression that VIOXX was safe for human use and constituted a safe form of a non-steroid anti-inflammatory drug.

14. The defendants failed to protect users from serious dangers that the defendants knew or should have known would result from the use of VIOXX.

15. The defendants failed to adequately disclose, warn, instruct and/or provide guidance to consumers concerning the health hazards and risks associated with the use of VIOXX, which were known or should have been known to the defendants.

16. The defendants engaged in the distribution and/or use of VIOXX without providing full and complete instructions and/or warnings.

17. The defendants failed to adequately and properly test and/or research the health effects of VIOXX.

18. The defendants engaged in this conduct knowing that VIOXX was being prescribed to people who were not aware of the serious cardiovascular risks of the drug.

19. The promotional campaign initiated, created, monitored, an/or supported by the defendants was intended to fraudulently induce and misrepresent in an affirmative manner the belief that through the use of VIOXX, arthritis and other pain could be managed with no serious or significant side effects or adverse reactions that would be experienced by the users of the drugs. This information was false, misleading, and fraudulent. At all times relevant herein, the defendants intentionally withheld and/or failed to adequately communicate known and/or potential health hazards and risks associated with the use of the drugs. The promotional campaign continued to create the false impression

of the successful and safe use of the drug, while at the same time the defendants were not communicating information regarding risks and complications that were known by or should have been known to the defendants.

20. The defendants fraudulently, deceptively, and unfairly misrepresented the facts regarding VIOXX, including but not limited to adequate testing of the drug and the efficiency, severity, frequency, and discomfort of side effects and adverse health effects caused by VIOXX.

21. As a result of the defendants' deceptive and unfair advertising and marketing practices, VIOXX was distributed throughout the United States and upon information and belief, over 1 million prescriptions for VIOXX were written in the United States, including Massachusetts, prior to the removal of VIOXX from the market.

22. The plaintiff began to consume VIOXX in August 2000 through approximately September 2004.

23. The plaintiff suffered a myocardial infarction while taking VIOXX.

24. On September 30, 2004, the defendant Merck announced a voluntary worldwide withdrawal of VIOXX from the market after the Adenomatous Polyp Prevention trial(APPROVe) confirmed the cardiovascular risks previously found in the VIGOR study.

**COUNT I**

**NEGLIGENCE**

25. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

26. It was the duty of the defendants to use and exercise reasonable and due care in the manufacture, development, design, formulation, testing, inspection, production, advertisement, promotion, marketing, sale and distribution of VIOXX.

27. It was also the duty of the defendant to provide detailed and adequate instructions relative to the proper and safe use of VIOXX and to provide detailed and adequate warnings concerning any and all dangers, characteristics, and potentialities of VIOXX, including known or suspected risks from the use of VIOXX, and to prevent a product which they knew or with reasonable care should have known was unreasonably dangerous and defective from entering the channels of trade.

28. It was the continuing duty of the defendants to advise and warn purchasers, consumer users, medical providers and other health care providers of all dangers, characteristics, potentialities and defects discovered subsequent to their initial marketing or sale of VIOXX.

29. Yet, nevertheless, wholly disregarding the aforesaid duties, the defendants breached their duties by:

a. unreasonable, careless and negligent conduct in the design, development, formulation, manufacture, advertisement, promotion, marketing, sale, and distribution of VIOXX;

b. failing to adequately test VIOXX;

c. failing to warn or instruct, or adequately warn or adequately instruct, physicians and medical providers concerning the risk or likelihood of, inter alia, cardiovascular events in individuals who have consumed VIOXX and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

d. failing to warn or instruct, or adequately warn or adequately instruct the plaintiff and consumers of VIOXX concerning the risk or likelihood of, inter alia, suffering cardiovascular events and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

e. by placing in the channels of trade a drug which defendants knew or with reasonable care should have known was unreasonably dangerous and unsafe and by placing VIOXX in the channel of trade in a manner which the defendants foresaw, or in the exercise of reasonable care ought to have foreseen, would carry VIOXX into contact with persons such as the plaintiff, and by

failing to use reasonable care to prevent injury to such persons, including the plaintiff.

f. marketing an inherently unsafe and/or dangerous drug;

g. misrepresenting that VIOXX was safe when the defendants knew, or in the exercise of reasonable care should have known, that VIOXX was dangerous and unsafe.

h. failing to provide adequate field and clinical testing both before and after marketing VIOXX;

i. failing to disclose known risks and instead minimizing the risks associated with the use of VIOXX in promotional campaigns and materials and oral representations.

j. failing to adequately warn of reactions, side effect, and complications associated with the use of VIOXX.

30. As a direct and proximate result of the unreasonable, careless, and negligent conduct of the defendants, the plaintiff, Vera Gropper, was caused to sustain severe and permanent injuries including a Myocardial Infarction, as a result of which the plaintiff has incurred medical expenses, incurred mental and physical pain and suffering, and suffered an impairment in her enjoyment of life, which damages are continuing in nature.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT II**

**BREACH OF EXPRESSED AND IMPLIED WARRANTIES**

31. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

32. The plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the defendants' products within the meaning of Massachusetts General Laws c. 106, §2-318, as the defendants knew or had reason to know that their products could cause serious cardiovascular injuries.

33. The defendants expressly and impliedly warranted that VIOXX was safe, merchantable, fit for consumption, and for the use for which it was intended and fit for its particular purpose to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, the management of acute pain in adults, and the treatment of primary dysmenorrheal.

34. The defendants knew or had reason to know of the particular purposes for which VIOXX would be used.

35. The plaintiff relied upon the defendants' skill or judgment to furnish or select a suitable product.

36. The defendants breached said warranties to the plaintiff because VIOXX was unsafe and not of merchantable quality.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT III**

**MALICIOUS, WILLFUL, WANTON, AND RECKLESS CONDUCT OR GROSS NEGLIGENCE**

37. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

38. At least by 2000, the defendants, or some of them, possessed medical and scientific data indicating that VIOXX posed potentially serious cardiovascular risks and as early as this date the defendants, or some of them, possessed medical and scientific data indicating that the use of VIOXX was potentially hazardous to the health and safety of Vera Gropper and others in her position.

39. Prompted by pecuniary motives, the defendants ignored and failed to act upon such medical and scientific data and deprived the public, and particularly the users, from access to said medical and scientific data, thereby depriving them of informed and free choice as to whether or not to consume VIOXX.

40. The defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, by continuing to market VIOXX with reckless disregard for the health and safety of

the plaintiff an others users and consumers, knowing the dangerous characteristics and propensities of VIOXX, but still depriving those affected by the dangers from information about those dangers.

41. Because the defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, in marketing their hazardous product, in ignoring the medical and scientific data which was available to them, and depriving consumers, users, and the general public from that medical and scientific data, the plaintiff is entitled to compensatory damages.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages plus interest and costs.

**COUNT IV**

**DEFECTIVE DESIGN/STRICT LIABILITY**

42. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

43. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling VIOXX that were defective and unreasonably dangerous to consumers, including Plaintiff.

44. At all times material hereto, VIOXX which were researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiff, without substantial change in the condition in which they were sold.

45. At all times material hereto, VIOXX was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

A. When placed in the stream of commerce, VIOXX contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of VIOXX;
B. When placed in the stream of commerce, VIOXX were defective in design and formulation, making use of VIOXX more dangerous than an ordinary consumer would expect;
C. VIOXX were insufficiently tested;
D. The intended use of VIOXX caused harmful side effects which outweighed any potential utility; and
E. VIOXX were not safe for its intended use as a weight loss drug.

COUNT V
FAILURE TO WARN/STRICT LIABILITY

48. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

48. VIOXX was defective and unreasonably dangerous when it left the possession of Defendants in that VIOXX contained warnings which were misleading regarding the purported benefits associated with VIOXX and were inadequate and insufficient to alert physicians and consumers, such as Plaintiff, to the dangerous risks and reactions associated with VIOXX, including, but not limited to, cardiovascular risks, including myocardial infarction and other serious and life threatening side affects. Plaintiff's injuries and losses are continuing in nature.

50. The physicians prescribed VIOXX to Plaintiff for the intended purpose.

51. Neither the prescribing physicians nor Plaintiff could have discovered any defect in VIOXX through the exercise of reasonable care.

52. Defendants are held to the level of knowledge of an expert in the field.

53. The prescribing physicians did not have substantially the same knowledge as an adequate warning from the manufacturer, distributor or sales representative should have communicated to the prescribing physician.

54. The warnings that were given by Defendants to the prescribing physicians were not adequate, accurate, or clear, and were ambiguous.

55. Defendants had a continuing duty to warn the prescribing physicians and Plaintiff of the dangers associated with VIOXX.

56. As a direct and legal result of Defendants' failure to warn, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for damages, as well as all costs of this action.

**COUNT VI**
**FRAUDULENT/NEGLIGENT MISREPRESENTATION**

57. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

58. Defendants, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of VIOXX owed a duty to provide complete and accurate information regarding VIOXX to Plaintiff, her physicians, and anyone else Defendants knew or should have known would ingest or prescribe VIOXX.

59. Defendants misrepresented material facts regarding the safety and efficacy of VIOXX, and failed to inform Plaintiff, the public and Plaintiff's prescribing physician of these material facts.

60. Defendants fraudulently and/or negligently misrepresented to Plaintiff, Plaintiff's physicians, the FDA, and the general

public that VIOXX was safe and effective, that the benefits of taking VIOXX outweighed any risks, and/or fraudulently and/or negligently misrepresented and concealed safety and effectiveness information regarding the product, including but not limited to VIOXX's propensity to cause serious physical harm. The continuous and ongoing course of action constituting fraudulent and/or negligent misrepresentation on Plaintiff started at least as early as 2000, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

61. VIOXX was in fact unsafe and the use of VIOXX posed a risk of injury and death which outweighed the purported benefits of its use, such that injury was in fact caused to Plaintiff and others.

62. Defendants made fraudulent and/or negligent misrepresentations regarding adverse information at a time when it knew, or should have known, that VIOXX had defects, dangers, and characteristics that were other than what Defendants had represented to the prescribing

doctors or other dispensing entities, the FDA, and the consuming public, including Plaintiff. Specifically, Defendants misrepresented the following:

a. It was dangerous to prescribe VIOXX;
b. VIOXX carried risks of serious, life threatening adverse effects;

63. The misrepresentations alleged above were perpetuated directly and indirectly by the Defendants.

64. The fraudulent and/or negligent misrepresentations of Defendants took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information regarding the products while having a duty to disclose to Plaintiff and others such information.

65. Defendants knew or should have known that these representations were misleading at the time they were made or omitted, and made the representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely

on them, leading to the use of VIOXX by Plaintiff.

66. At the time of Defendants' fraudulent and/or negligent misrepresentations, Plaintiff and Plaintiff' physicians were unaware of the inaccuracy of the statements being made and believed them to be true.

67. Plaintiff's physician and Plaintiff justifiably relied on and were induced by the misrepresentations and relied on the absence of adverse safety information in the prescription and ingestion of VIOXX.

68. Defendants had a post-sale duty to warn Plaintiff and or Plaintiff's physicians about the potential risks and complications associated with VIOXX in a timely manner.

69. The misrepresentations by Defendants constitute a continuing tort.

70. Defendants made the statements and/or omissions with the intention that Plaintiff, Plaintiff's prescribing physicians or other dispensing entities and the consuming public would rely on such or the absence of such

information in selecting VIOXX as a treatment for arthritis and pain management.

71. As a direct and legal result of the fraudulent and/or negligent misrepresentations of Defendants, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages, plus interest and costs.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues.

WHEREFORE, the plaintiff prays:

1. The judgment enter against the defendants on all Counts of this Complaint;

2. That plaintiff be awarded full, fair and complete compensation, for which she is legally entitled;
3. That the plaintiff be awarded full, fair, and complete compensation plus treble amount, attorney's fees and costs under M.G.L. c. 93A, §§ 2 and 9;
4. that plaintiff be awarded all appropriate costs, attorney's fees and interest authorized by law;
5. That the court enter such other relief as is determined just and appropriate.

Respectfully Submitted,

David C. Strouss (BBO#546253)
Marilyn T. McGoldrick, (BBO#561766)
Allyson S. Hauck (BBO#659547)
THORNTON & NAUMES, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
(617)720-1333

Dated: October 29, 2004

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss. SUPERIOR COURT
DEPT. OF THE TRIAL
COURT 04-4301

VERA GROPPER,
Plaintiff

vs.

MERCK & CO., INC.,
and John and Jane Does, as
Sales representatives for
MERCK & CO., INC.,
Defendants.

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
FOR THE COUNTY OF MIDDLESEX
JAN 12 2005
CLERK

NOTICE OF ADDITION OF VIOLATION OF M.G.L. c.93A
COUNT AND FILING OF FIRST AMENDED COMPLAINT

Now come the plaintiff, pursuant to Mass. R. Civ. P. 15(a) and files the attached First Amended Complaint in regard to the above-captioned matter.

The First Amended Complaint reflects the addition of a count for violation of the Consumer Protection Act, M.G.L. c. 93A against all defendants. In support

of this notice, plaintiff's counsel states that no responsive pleading has been served.

Respectfully submitted,

David C. Strouss, BBO#546253
Marilyn T. McGoldrick, BBO#561766
Allyson S. Hauck, BBO# 659547
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
(617) 720-1333

DATED: 1/12/05

CERTIFICATE OF SERVICE

I, Allyson S. Hauck, Esquire, hereby certify that on this day I mailed, postage prepaid, a copy of the foregoing Notice of Addition of M.G.L. c. 93A Count and Filing of First Amended Complaint to all defendants' counsel of records in the above-captioned matter.

DATED: 1/12/05

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
DEPT. OF THE TRIAL
COURT

VERA GROPPER,
Plaintiff

vs.

[redacted] & CO., INC.,
[redacted] John and Jane Does, as
[redacted] are unknown to
[redacted] & CO., INC.,
Defendants

FIRST AMENDED
COMPLAINT

Now comes the Plaintiff, by her attorneys, and files the following complaint:

Party Plaintiff

1. The Plaintiff, Vera Gropper, resides at 14 Hall Avenue, Somerville, Massachusetts, 02144, and at all relevant times herein, was a resident of the Commonwealth of Massachusetts.

Party Defendants

2A. The Defendant, Merck & Co., Inc., (hereinafter, "Merck") is a corporation incorporated under the laws of the State of New Jersey, having a principal place of business in the State of New Jersey, and has conducted business in the Commonwealth of Massachusetts. At all relevant times hereto, Merck was in the

business of promoting, marketing, and distributing the pharmaceutical VIOXX(Refecoxib).

2b. John and Jane Does are sales representatives for Merck promoting and distributing VIOXX to physicians within the Commonwealth of Massachusetts. Upon information and belief all or some of the John and Jane Doe Sales Representatives are individuals residing in the Commonwealth of Massachusetts.

As used in this Complaint, the term "defendant" shall include any party defendants identified in paragraphs 2a through 2b hereof, and their predecessors, which shall include, but is not limited to, any person, corporation, company or business entity: which formed part of any combination, consolidation, merger or reorganization from which any party defendant was created or was the surviving corporation; whose assets, stock, property, products or product line was acquired by any party defendant; whose patent rights, trademark rights, trade secrets of goodwill was acquired by any party defendant; or which was dominated or controlled by any party defendant to such an extent that said party defendant was the "alter ego" of said corporation.

**JURISDICTION**

3. The plaintiff's cause of action arises from the defendants' (1) transacting business in Massachusetts; (2) contracting to supply and/or sell goods in Massachusetts; (3) doing or causing

a tortuous act to be done in Massachusetts; and/or (4) causing the consequence of a tortuous act to occur within Massachusetts, and the defendants do, or solicit business, or engage in a persistent course of conduct or derive substantial revenue from the sale of goods in Massachusetts.

**FACTS**

4. At all relevant times herein, the defendants individually and/or in conjunction with other persons or entities for whose conduct they were legally responsible developed, created, manufactured, designed, tested, labeled, packaged, distributed, supplied, marketed, sold, advertised, and/or otherwise distributed in interstate trade and commerce the drug VIOXX.

5. On information and belief, the drugs were manufactured, distributed, and sold as medication to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, for the management of acute pain in adults, and the treatment of primary dysmenorrheal.

6. In May of 1999 VIOXX was approved by the FDA. The defendants individually began actively and aggressively promoting, marketing and selling the drug in the United States and eighty other countries. The defendants fraudulently induced people to use its drug for arthritis and pain relief without adequately warning people of the risks associated with the drug that were known or should have been known to the defendants.

7. The defendants engaged in a nationwide marketing scheme including but not limited to the Commonwealth of Massachusetts and participated in advertisements and promotional enhancements and literature, directly targeting consumers and various physicians and other health care providers.

8. The defendants, engaged in the study "VIOXX GATROINTESTINAL OUTCOMES RESEACH" ("VIGOR"). The results of the study were released in March 2000 and the findings demonstrated that VIOXX patients were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on Naprosyn (Naproxen).

9. On information and believe, MERCK mislead patients and health care providers by using press releases, promotional materials and oral representations made by MERCK and through MERCK's sales representatives, to offer an untested hypothetical explanation to assert that VIOXX did not cause an increase in MIs as demonstrated in the VIGOR study.

10. On September 17, 2001 a warning letter was sent by the Department of Health and Human Services, Food and Drug Administration (FDA), requiring MERCK to end all violative promotional materials and send "dear Healthcare provider" letters to communicate the accurate findings and risks of VIOXX demonstrated in the VIGOR study.

11. The Defendant MERCK did not communicate the findings of cardiovascular risks from the

VIGOR study until April 2002 when they sent a "Dear Doctor" letter and made changes and additions to VIOXX label regarding cardiovascular risks under the header "Precautions". MERK did not add stroke or any of the other adverse reactions linked to VIOXX that it knew or should have known.

12. The defendants engaged in and/or actively participated in inducing and/or encouraging use of VIOXX by providing incentives for its use and by encouraging physicians and other health care providers to prescribe it without the benefit of the full and complete information known to the defendants. The defendants disseminated false and misleading materials which failed to disclose the risks associated with the use of VIOXX.

13. Upon information and belief, the defendants also unfairly and deceptively encouraged the use of VIOXX, by falsely misleading potential users including the plaintiff, Vera Gropper, concerning the risks associated with its use. By affirmative misrepresentations and omission, the defendants sought to create the impression that VIOXX was safe for human use and constituted a safe form of a non-steroid anti-inflammatory drug.

14. The defendants failed to protect users from serious dangers that the defendants knew or should have known would result from the use of VIOXX.

15. The defendants failed to adequately disclose, warn, instruct and/or provide guidance to consumers concerning the health hazards and risks associated with the use of VIOXX, which were known or should have been known to the defendants.

16. The defendants engaged in the distribution and/or use of VIOXX without providing full and complete instructions and/or warnings.

17. The defendants failed to adequately and properly test and/or research the health effects of VIOXX.

18. The defendants engaged in this conduct knowing that VIOXX was being prescribed to people who were not aware of the serious cardiovascular risks of the drug.

19. The promotional campaign initiated, created, monitored, an/or supported by the defendants was intended to fraudulently induce and misrepresent in an affirmative manner the belief that through the use of VIOXX, arthritis and other pain could be managed with no serious or significant side effects or adverse reactions that would be experienced by the users of the drugs. This information was false, misleading, and fraudulent. At all times relevant herein, the defendants intentionally withheld and/or failed to adequately communicate known and/or potential health hazards and risks associated with the use of the drugs. The promotional campaign continued to create the false impression

of the successful and safe use of the drug, while at the same time the defendants were not communicating information regarding risks and complications that were known by or should have been known to the defendants.

20. The defendants fraudulently, deceptively, and unfairly misrepresented the facts regarding VIOXX, including but not limited to adequate testing of the drug and the efficiency, severity, frequency, and discomfort of side effects and adverse health effects caused by VIOXX.

21. As a result of the defendants' deceptive and unfair advertising and marketing practices, VIOXX was distributed throughout the United States and upon information and belief, over 1 million prescriptions for VIOXX were written in the United States, including Massachusetts, prior to the removal of VIOXX from the market.

22. The plaintiff began to consume VIOXX in August 2000 through approximately September 2004.

23. The plaintiff suffered a myocardial infarction while taking VIOXX.

24. On September 30, 2004, the defendant Merck announced a voluntary worldwide withdrawal of VIOXX from the market after the Adenomatous Polyp Prevention trial (APPROVe) confirmed the cardiovascular risks previously found in the VIGOR study.

**COUNT I**

**NEGLIGENCE**

25. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

26. It was the duty of the defendants to use and exercise reasonable and due care in the manufacture, development, design, formulation, testing, inspection, production, advertisement, promotion, marketing, sale and distribution of VIOXX.

27. It was also the duty of the defendant to provide detailed and adequate instructions relative to the proper and safe use of VIOXX and to provide detailed and adequate warnings concerning any and all dangers, characteristics, and potentialities of VIOXX, including known or suspected risks from the use of VIOXX, and to prevent a product which they knew or with reasonable care should have known was unreasonably dangerous and defective from entering the channels of trade.

28. It was the continuing duty of the defendants to advise and warn purchasers, consumer, users, medical providers and other health care providers of all dangers, characteristics, potentialities and defects discovered subsequent to their initial marketing or sale of VIOXX.

29. Yet, nevertheless, wholly disregarding the aforesaid duties, the defendants breached their duties by:

a. unreasonable, careless and negligent conduct in the design, development, formulation, manufacture, advertisement, promotion, marketing, sale, and distribution of VIOXX;

b. failing to adequately test VIOXX;

c. failing to warn or instruct, or adequately warn or adequately instruct, physicians and medical providers concerning the risk or likelihood of, inter alia, cardiovascular events in individuals who have consumed VIOXX and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

d. failing to warn or instruct, or adequately warn or adequately instruct the plaintiff and consumers of VIOXX concerning the risk or likelihood of, inter alia, suffering cardiovascular events and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

e. by placing in the channels of trade a drug which defendants knew or with reasonable care should have known was unreasonably dangerous and unsafe and by placing VIOXX in the channel of trade in a manner which the defendants foresaw, or in the exercise of reasonable care ought to have foreseen, would carry VIOXX into contact with persons such as the plaintiff, and by failing to use reasonable care to prevent injury to such persons, including the plaintiff.

f. marketing an inherently unsafe and/or dangerous drug;

g. misrepresenting that VIOXX was safe when the defendants knew, or in the exercise of reasonable care should have known, that VIOXX was dangerous and unsafe.

h. failing to provide adequate field and clinical testing both before and after marketing VIOXX;

i. failing to disclose known risks and instead minimizing the risks associated with the use of VIOXX in promotional campaigns and materials and oral representations.

j. failing to adequately warn of reactions, side effect, and complications associated with the use of VIOXX.

30. As a direct and proximate result of the unreasonable, careless, and negligent conduct of the defendants, the plaintiff, Vera Gropper, was caused to sustain severe and permanent injuries including a Myocardial Infarction, as a result of which the plaintiff has incurred medical expenses, incurred mental and physical pain and suffering, and suffered an impairment in her enjoyment of life, which damages are continuing in nature.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT II**

**BREACH OF EXPRESSED AND IMPLIED WARRANTIES**

31. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

32. The plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the defendants' products within the meaning of Massachusetts General Laws c. 106, §2-318, as the defendants knew or had reason to know that their products could cause serious cardiovascular injuries.

33. The defendants expressly and impliedly warranted that VIOXX was safe, merchantable, fit for consumption, and for the use for which it was intended and fit for its particular purpose to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, the management of acute pain in adults, and the treatment of primary dysmenorrheal.

34. The defendants knew or had reason to know of the particular purposes for which VIOXX would be used.

35. The plaintiff relied upon the defendants' skill or judgment to furnish or select a suitable product.

36. The defendants breached said warranties to the plaintiff because VIOXX was unsafe and not of merchantable quality.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT III**

**MALICIOUS, WILLFUL, WANTON, AND RECKLESS CONDUCT OR GROSS NEGLIGENCE**

37. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

38. At least by 2000, the defendants, or some of them, possessed medical and scientific data indicating that VIOXX posed potentially serious cardiovascular risks and as early as this date the defendants, or some of them, possessed medical and scientific data indicating that the use of VIOXX was potentially hazardous to the health and safety of Vera Gropper and others in her position.

39. Prompted by pecuniary motives, the defendants ignored and failed to act upon such medical and scientific data and deprived the public, and particularly the users, from access to said medical and scientific data, thereby depriving them of informed and free choice as to whether or not to consume VIOXX.

40. The defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, by continuing to market VIOXX with reckless disregard for the health and safety of the plaintiff an others users and consumers, knowing the dangerous characteristics and propensities of VIOXX, but still depriving those

affected by the dangers from information about those dangers.

41. Because the defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, in marketing their hazardous product, in ignoring the medical and scientific data which was available to them, and depriving consumers, users, and the general public from that medical and scientific data, the plaintiff is entitled to compensatory damages.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages plus interest and costs.

**COUNT IV**

**DEFECTIVE DESIGN/STRICT LIABILITY**

42. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

43. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling VIOXX that were defective and unreasonably dangerous to consumers, including Plaintiff.

44. At all times material hereto, VIOXX which were researched, formulated, tested,

developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiff, without substantial change in the condition in which they were sold.

45. At all times material hereto, VIOXX was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

A. When placed in the stream of commerce, VIOXX contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of VIOXX;
B. When placed in the stream of commerce, VIOXX were defective in design and formulation, making use of VIOXX more dangerous than an ordinary consumer would expect;
C. VIOXX were insufficiently tested;
D. The intended use of VIOXX caused harmful side effects which outweighed any potential utility; and
E. VIOXX were not safe for its intended use as a weight loss drug.

46. But for the aforementioned defective and unreasonably dangerous conditions, VIOXX would not have been prescribed to Plaintiff, Plaintiff would not have ingested VIOXX, and Plaintiff would not have sustained the injuries alleged herein.

47. As a direct and legal result of the defective condition of VIOXX, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages plus interest and costs.

**COUNT V**
**FAILURE TO WARN/STRICT LIABILITY**

48. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

48. VIOXX was defective and unreasonably dangerous when it left the possession of Defendants in that VIOXX contained warnings which were misleading regarding the purported benefits associated with VIOXX and were inadequate and insufficient to alert physicians and consumers, such as Plaintiff, to the dangerous risks and reactions associated with VIOXX, including, but not limited to, cardiovascular risks, including myocardial infarction and other serious and life threatening side affects. Plaintiff's injuries and losses are continuing in nature.

50. The physicians prescribed VIOXX to Plaintiff for the intended purpose.

51. Neither the prescribing physicians nor Plaintiff could have discovered any defect in VIOXX through the exercise of reasonable care.

52. Defendants are held to the level of knowledge of an expert in the field.

53. The prescribing physicians did not have substantially the same knowledge as an adequate warning from the manufacturer, distributor or sales representative should have communicated to the prescribing physician.

54. The warnings that were given by Defendants to the prescribing physicians were not adequate, accurate, or clear, and were ambiguous.

55. Defendants had a continuing duty to warn the prescribing physicians and Plaintiff of the dangers associated with VIOXX.

56. As a direct and legal result of Defendants' failure to warn, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for damages, as well as all costs of this action.

**COUNT VI**
**FRAUDULENT/NEGLIGENT MISREPRESENTATION**

57. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

58. Defendants, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of VIOXX owed a duty to provide complete and accurate information regarding VIOXX to Plaintiff, her physicians, and anyone else Defendants knew or should have known would ingest or prescribe VIOXX.

59. Defendants misrepresented material facts regarding the safety and efficacy of VIOXX, and failed to inform Plaintiff, the public and Plaintiff's prescribing physician of these material facts.

60. Defendants fraudulently and/or negligently misrepresented to Plaintiff, Plaintiff's physicians, the FDA, and the general

public that VIOXX was safe and effective, that the benefits of taking VIOXX outweighed any risks, and/or fraudulently and/or negligently misrepresented and concealed safety and effectiveness information regarding the product, including but not limited to VIOXX's propensity to cause serious physical harm. The continuous and ongoing course of action constituting fraudulent and/or negligent misrepresentation on Plaintiff started at least as early as 2000, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

61. VIOXX was in fact unsafe and the use of VIOXX posed a risk of injury and death which outweighed the purported benefits of its use, such that injury was in fact caused to Plaintiff and others.

62. Defendants made fraudulent and/or negligent misrepresentations regarding adverse information at a time when it knew, or should have known, that VIOXX had defects, dangers, and characteristics that were other than what Defendants had represented to the prescribing

doctors or other dispensing entities, the FDA, and the consuming public, including Plaintiff. Specifically, Defendants misrepresented the following:

a. It was dangerous to prescribe VIOXX;
b. VIOXX carried risks of serious, life threatening adverse effects;

63. The misrepresentations alleged above were perpetuated directly and indirectly by the Defendants.

64. The fraudulent and/or negligent misrepresentations of Defendants took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information regarding the products while having a duty to disclose to Plaintiff and others such information.

65. Defendants knew or should have known that these representations were misleading at the time they were made or omitted, and made the representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely

on them, leading to the use of VIOXX by Plaintiff.

66. At the time of Defendants' fraudulent and/or negligent misrepresentations, Plaintiff and Plaintiff' physicians were unaware of the inaccuracy of the statements being made and believed them to be true.

67. Plaintiff's physician and Plaintiff justifiably relied on and were induced by the misrepresentations and relied on the absence of adverse safety information in the prescription and ingestion of VIOXX.

68. Defendants had a post-sale duty to warn Plaintiff and or Plaintiff's physicians about the potential risks and complications associated with VIOXX in a timely manner.

69. The misrepresentations by Defendants constitute a continuing tort.

70. Defendants made the statements and/or omissions with the intention that Plaintiff, Plaintiff's prescribing physicians or other dispensing entities and the consuming public would rely on such or the absence of such

information in selecting VIOXX as a treatment for arthritis and pain management.

71. As a direct and legal result of the fraudulent and/or negligent misrepresentations of Defendants, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages, plus interest and costs.

**Count VII**

**Violation of M.G.L. c.93A**

72. The plaintiff repeats, realleges, and reavers paragraphs one through seventy-one above as if expressly set forth fully hereinafter.

73. At all relevant times hereto the defendants were engaged in trade or commerce.

74. The acts of the defendants alleged in Counts I through VI, and as outlined in the Facts, constitute unfair or deceptive acts or practices within the meaning of G.L. c. 93A, §§ 2 and 3, 940 C.M.R. 3.05(1), and 940 C.M.R. 3.16(1) and (2).

75. The actions of the defendants described herein were performed willfully and knowingly.

76. As a result of the unfair or deceptive acts or practices described in the Facts, the plaintiff sustained injury including but not limited to the injuries stated in Paragraph 23 above, incorporated herein.

Wherefore, the plaintiff, Vera Gropper demands judgment against the defendants in an amount that is

fair and reasonable; plus treble such amount as provided by M.G.L. c. 93A, sec. 9(3); plus interest, costs and attorneys' fees to the plaintiff; and award such other relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues.

WHEREFORE, the plaintiff prays:

1. The judgment enter against the defendants on all Counts of this Complaint;
2. That plaintiff be awarded full, fair and complete compensation, for which she is legally entitled;
3. That the plaintiff be awarded full, fair, and complete compensation plus treble amount, attorney's fees and costs under M.G.L. c. 93A, §§ 2 and 9;
4. that plaintiff be awarded all appropriate costs, attorney's fees and interest authorized by law;
5. That the court enter such other relief as is determined just and appropriate.

Respectfully Submitted,

David C. Strouss (BBO#546253)
Marilyn T. McGoldrick, (BBO#561766)
Allyson S. Hauck (BBO#659547)
THORNTON & NAUMES, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
(617)720-1333

Dated: January 5, 2005

# CIVIL ACTION COVER SHEET

DOCKET NO.(S) 2004-4301

**Trial Court of Massachusetts**
**Superior Court Department**
County: MIDDLESEX

| PLAINTIFF(S) | DEFENDANT(S) |
|---|---|
| Vera Gropper | MERCK & CO., INC., et al. |
| ATTORNEY, FIRM, ADDRESS AND TELEPHONE<br>(617)720-1333<br>David Strouss, Esquire BBO #546253<br>Marilyn McGoldrick, Esquire BBO #561766<br>Allyson Hauck, Esquire, BBO #659547<br>THORNTON & NAUMES, LLP<br>100 Summer St., 30th Fl., Boston, MA 02110<br>Board of Bar Overseers number: listed above | ATTORNEY (if known) |

## Origin code and track designation

Place and x in one box only:

- [x] 1.F01 Original Complaint
- [ ] 2.F02 Removal to Sup.Ct. C.231, s.104 (Before trial) (F)
- [ ] 3.F03 Retransfer to Sup.Ct.C.231,s.102C(X)
- [ ] 4.F04 District Court Appeal c.231,s.97 & 104 (After trial) (X)
- [ ] 5.F05 Reactivated after rescript; relief from judgment/Order (Mass.R.Civ.P.60) (X)
- [ ] 6.E10 Summary Process Appeal (X)

**TYPE OF ACTION AND TRACK DESIGNATION (See Reverse Side)**

| CODE NO. | TYPE OF ACTION (specify) | TRACK | IS THIS A JURY CASE? |
|---|---|---|---|
| B05 | Product Liability | (A) | (X) Yes ( ) No |

**The following is a full, itemized and detailed statement of the facts on which plaintiff relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.**

## TORT CLAIMS

(Attach additional sheets as necessary)

| | | |
|---|---|---|
| A. | Documented medical expenses to date: | |
| | 1. Total hospital expenses | $..see attached.. |
| | 2. Total Doctor expenses | $..see attached.. |
| | 3. Total chiropractic expenses | $..see attached.. |
| | 4. Total physical therapy expenses | $..see attached.. |
| | 5. Total other expenses (describe) | $..see attached.. |
| B. | Documented lost wages and compensation to date | $..see attached.. |
| | **Subtotal** | **$..see attached..** |
| C. | Documented property damages to date | $..see attached.. |
| D. | Reasonably anticipated future medical and hospital expenses | $..see attached.. |
| E. | Reasonably anticipated lost wages | $..see attached.. |
| F. | Other documented items of damages (describe) | $..see attached.. |
| G. | Brief description of plaintiff's injury, including nature and extent of injury (describe) | $..see attached.. |

Plaintiff suffered injuries out of her use of Vioxx manufactured, sold, promoted and supplied by the Defendants. In light of the damages, Plaintiff believes there is a reasonable likelihood that recovery will be in excess of $25,000.

$1,200,000.00
$..see attached..

## CONTRACT CLAIMS

(Attach additional sheets as necessary)

Provide a detailed description of claim(s):

**TOTAL $.....**

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT- None

**"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods."**

Signature of Attorney of Record _____ DATE: 11/4/04

_____, Esq.

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
DEPT. OF THE TRIAL COURT

VERA GROPPER,

Plaintiff,

v.

MERCK & CO., INC., and John and Jane Does, as Sales Representatives for MERCK & CO, INC.,

Defendants.

C. A. No. 04-4301

**NOTICE OF FILING**
**NOTICE OF REMOVAL**

TO THE CLERK OF THE ABOVE-ENTITLED COURT:

Please take notice that on February 3, 2005, defendant Merck & Co., Inc. filed the attached Notice of Removal in the United States District Court for the District of Massachusetts.

MERCK & CO., INC.
By its attorneys:

James J. Dillon (BBO# 124660)
Bradley E. Abruzzi (BBO# 651516)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110-2600
(617) 832-1000

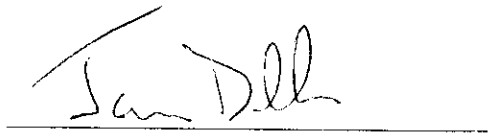
Dated: February 3, 2005

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
FOR THE COUNTY OF MIDDLESEX
FEB 4 2005
CLERK

**CERTIFICATE OF SERVICE**

I certify that a true copy of the foregoing NOTICE OF FILING NOTICE OF REMOVAL was served on February 3, 2005 by hand, upon:

David C. Strouss
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
**Counsel for Plaintiff Vera Gropper**



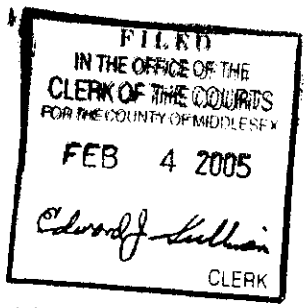
FOLEY HOAG LLP
ATTORNEYS AT LAW

Brad Abruzzi
Boston Office
617/832-1291
babruzzi@foleyhoag.com

February 3, 2005

**By Hand**

Clerk's Office
Middlesex Superior Court
40 Thorndike Street
Cambridge, Massachusetts 02141




Re: Gropper v. Merck & Co., Inc., 04-4301

Dear Sir/Madam:

Enclosed for filing in the above-entitled action is Notice of Filing Notice of Removal attached to which is a copy of the Notice of Removal filed February 3, 2005 in the United States District Court for the District of Massachusetts. Pursuant to 28 U.S.C. § 1446(a), the filing of this Notice effects the removal of this action from this Court.

In accordance with Rule 81.1 of the Local Rules of the United States District Court for the District of Massachusetts, the defendant is required to file with that Court certified copies of all papers filed in this action, including the enclosed Notice and a certified copy of the docket sheet. Accordingly, after you have filed and docketed the enclosed Notice, please prepare certified copies of all case papers and the docket in this action and forward them to my attention.

Thank you for your assistance in this matter.

Sincerely,

Brad Abruzzi

BEA

cc: James A. Dillon, Esq.
David C. Strouss, Esq.

FHBOSTON/2175459.1

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
DEPT. OF THE TRIAL
COURT

04-4301

VERA GROPPER,
Plaintiff

vs.

MERCK & CO., INC.,
and John and Jane Does, as
Sales representatives for
MERCK & CO., INC.,
Defendants.

COMPLAINT





Now comes the plaintiff, by her attorney, and files the following complaint:

1. Party Plaintiff

The Plaintiff, Vera Gropper, resides at 14 Hall Avenue, Somerville, Massachusetts, 02144, and at all relevant times herein, was a resident of the Commonwealth of Massachusetts.

2. Party Defendants

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business of promoting, marketing, and distributing the pharmaceutical VIOXX(Refecoxib).

2b. John and Jane Does are sales representatives for Merck promoting and distributing VIOXX to physicians within the Commonwealth of Massachusetts. Upon information and belief all or some of the John and Jane Doe Sales Representatives are individuals residing in the Commonwealth of Massachusetts.

As used in this Complaint, the term "defendant" shall include any party defendants identified in paragraphs 2a through 2b hereof, and their predecessors, which shall include, but is not limited to, any person, corporation, company or business entity: which formed part of any combination, consolidation, merger or reorganization from which any party defendant was created or was the surviving corporation; whose assets, stock, property, products or product line was acquired by any party defendant; whose patent rights, trademark rights, trade secrets of goodwill was acquired by any party defendant; or which was dominated or controlled by any party defendant to such an extent that said party defendant was the "alter ego" of said corporation.

**JURISDICTION**

3. The plaintiff's cause of action arises from the defendants' (1) transacting business in Massachusetts; (2) contracting to supply and/or sell goods in Massachusetts; (3) doing or causing

a tortuous act to be done in Massachusetts; and/or (4) causing the consequence of a tortuous act to occur within Massachusetts, and the defendants do, or solicit business, or engage in a persistent course of conduct or derive substantial revenue from the sale of goods in Massachusetts.

**FACTS**

4. At all relevant times herein, the defendants individually and/or in conjunction with other persons or entities for whose conduct they were legally responsible developed, created, manufactured, designed, tested, labeled, packaged, distributed, supplied, marketed, sold, advertised, and/or otherwise distributed in interstate trade and commerce the drug VIOXX.

5. On information and belief, the drugs were manufactured, distributed, and sold as medication to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, for the management of acute pain in adults, and the treatment of primary dysmenorrheal.

6. In May of 1999 VIOXX was approved by the FDA. The defendants individually began actively and aggressively promoting, marketing and selling the drug in the United States and eighty other countries. The defendants fraudulently induced people to use its drug for arthritis and pain relief without adequately warning people of the risks associated with the drug that were known or should have been known to the defendants.

7. The defendants engaged in a nationwide marketing scheme including but not limited to the Commonwealth of Massachusetts and participated in advertisements and promotional enhancements and literature, directly targeting consumers and various physicians and other health care providers.

8. The defendants, engaged in the study "VIOXX GATROINTESTINAL OUTCOMES RESEACH" ("VIGOR"). The results of the study were released in March 2000 and the findings demonstrated that VIOXX patients were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on Naprosyn (Naproxen).

9. On information and believe, MERCK mislead patients and health care providers by using press releases, promotional materials and oral representations made by MERCK and through MERCK's sales representatives, to offer an untested hypothetical explanation to assert that VIOXX did not cause an increase in MIs as demonstrated in the VIGOR study.

10. On September 17, 2001 a warning letter was sent by the Department of Health and Human Services, Food and Drug Administration (FDA), requiring MERCK to end all violative promotional materials and send "dear Healthcare provider" letters to communicate the accurate findings and risks of VIOXX demonstrated in the VIGOR study.

11. The Defendant MERCK did not communicate the findings of cardiovascular risks from the

VIGOR study until April 2002 when they sent a "Dear Doctor" letter and made changes and additions to VIOXX label regarding cardiovascular risks under the header "Precautions". MERK did not add stroke or any of the other adverse reactions linked to VIOXX that it knew or should have known.

12. The defendants engaged in and/or actively participated in inducing and/or encouraging use of VIOXX by providing incentives for its use and by encouraging physicians and other health care providers to prescribe it without the benefit of the full and complete information known to the defendants. The defendants disseminated false and misleading materials which failed to disclose the risks associated with the use of VIOXX.

13. Upon information and belief, the defendants also unfairly and deceptively encouraged the use of VIOXX, by falsely misleading potential users including the plaintiff, Vera Gropper, concerning the risks associated with its use. By affirmative misrepresentations and omission, the defendants sought to create the impression that VIOXX was safe for human use and constituted a safe form of a non-steroid anti-inflammatory drug.

14. The defendants failed to protect users from serious dangers that the defendants knew or should have known would result from the use of VIOXX.

15. The defendants failed to adequately disclose, warn, instruct and/or provide guidance to consumers concerning the health hazards and risks associated with the use of VIOXX, which were known or should have been known to the defendants.

16. The defendants engaged in the distribution and/or use of VIOXX without providing full and complete instructions and/or warnings.

17. The defendants failed to adequately and properly test and/or research the health effects of VIOXX.

18. The defendants engaged in this conduct knowing that VIOXX was being prescribed to people who were not aware of the serious cardiovascular risks of the drug.

19. The promotional campaign initiated, created, monitored, an/or supported by the defendants was intended to fraudulently induce and misrepresent in an affirmative manner the belief that through the use of VIOXX, arthritis and other pain could be managed with no serious or significant side effects or adverse reactions that would be experienced by the users of the drugs. This information was false, misleading, and fraudulent. At all times relevant herein, the defendants intentionally withheld and/or failed to adequately communicate known and/or potential health hazards and risks associated with the use of the drugs. The promotional campaign continued to create the false impression

of the successful and safe use of the drug, while at the same time the defendants were not communicating information regarding risks and complications that were known by or should have been known to the defendants.

20. The defendants fraudulently, deceptively, and unfairly misrepresented the facts regarding VIOXX, including but not limited to adequate testing of the drug and the efficiency, severity, frequency, and discomfort of side effects and adverse health effects caused by VIOXX.

21. As a result of the defendants' deceptive and unfair advertising and marketing practices, VIOXX was distributed throughout the United States and upon information and belief, over 1 million prescriptions for VIOXX were written in the United States, including Massachusetts, prior to the removal of VIOXX from the market.

22. The plaintiff began to consume VIOXX in August 2000 through approximately September 2004.

23. The plaintiff suffered a myocardial infarction while taking VIOXX.

24. On September 30, 2004, the defendant Merck announced a voluntary worldwide withdrawal of VIOXX from the market after the Adenomatous Polyp Prevention trial (APPROVe) confirmed the cardiovascular risks previously found in the VIGOR study.

29. Yet, nevertheless, wholly disregarding the aforesaid duties, the defendants breached their duties by:

a. unreasonable, careless and negligent conduct in the design, development, formulation, manufacture, advertisement, promotion, marketing, sale, and distribution of VIOXX;

b. failing to adequately test VIOXX;

c. failing to warn or instruct, or adequately warn or adequately instruct, physicians and medical providers concerning the risk or likelihood of, inter alia, cardiovascular events in individuals who have consumed VIOXX and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

d. failing to warn or instruct, or adequately warn or adequately instruct the plaintiff and consumers of VIOXX concerning the risk or likelihood of, inter alia, suffering cardiovascular events and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

e. by placing in the channels of trade a drug which defendants knew or with reasonable care should have known was unreasonably dangerous and unsafe and by placing VIOXX in the channel of trade in a manner which the defendants foresaw, or in the exercise of reasonable care ought to have foreseen, would carry VIOXX into contact with persons such as the plaintiff, and by

## COUNT II

## BREACH OF EXPRESSED AND IMPLIED WARRANTIES

31. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

32. The plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the defendants' products within the meaning of Massachusetts General Laws c. 106, §2-318, as the defendants knew or had reason to know that their products could cause serious cardiovascular injuries.

33. The defendants expressly and impliedly warranted that VIOXX was safe, merchantable, fit for consumption, and for the use for which it was intended and fit for its particular purpose to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, the management of acute pain in adults, and the treatment of primary dysmenorrheal.

34. The defendants knew or had reason to know of the particular purposes for which VIOXX would be used.

35. The plaintiff relied upon the defendants' skill or judgment to furnish or select a suitable product.

36. The defendants breached said warranties to the plaintiff because VIOXX was unsafe and not of merchantable quality.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT III**

**MALICIOUS, WILLFUL, WANTON, AND RECKLESS CONDUCT OR GROSS NEGLIGENCE**

37. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

38. At least by 2000, the defendants, or some of them, possessed medical and scientific data indicating that VIOXX posed potentially serious cardiovascular risks and as early as this date the defendants, or some of them, possessed medical and scientific data indicating that the use of VIOXX was potentially hazardous to the health and safety of Vera Gropper and others in her position.

39. Prompted by pecuniary motives, the defendants ignored and failed to act upon such medical and scientific data and deprived the public, and particularly the users, from access to said medical and scientific data, thereby depriving them of informed and free choice as to whether or not to consume VIOXX.

40. The defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, by continuing to market VIOXX with reckless disregard for the health and safety of

the plaintiff an others users and consumers, knowing the dangerous characteristics and propensities of VIOXX, but still depriving those affected by the dangers from information about those dangers.

41. Because the defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, in marketing their hazardous product, in ignoring the medical and scientific data which was available to them, and depriving consumers, users, and the general public from that medical and scientific data, the plaintiff is entitled to compensatory damages.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages plus interest and costs.

**COUNT IV**

**DEFECTIVE DESIGN/STRICT LIABILITY**

42. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

43. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling VIOXX that were defective and unreasonably dangerous to consumers, including Plaintiff.

44. At all times material hereto, VIOXX which were researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiff, without substantial change in the condition in which they were sold.

45. At all times material hereto, VIOXX was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

A. When placed in the stream of commerce, VIOXX contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of VIOXX;
B. When placed in the stream of commerce, VIOXX were defective in design and formulation, making use of VIOXX more dangerous than an ordinary consumer would expect;
C. VIOXX were insufficiently tested;
D. The intended use of VIOXX caused harmful side effects which outweighed any potential utility; and
E. VIOXX were not safe for its intended use as a weight loss drug.

46. But for the aforementioned defective and unreasonably dangerous conditions, VIOXX would not have been prescribed to Plaintiff, Plaintiff would not have ingested VIOXX, and Plaintiff would not have sustained the injuries alleged herein.

47. As a direct and legal result of the defective condition of VIOXX, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages plus interest and costs.

COUNT V
FAILURE TO WARN/STRICT LIABILITY

48. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

48. VIOXX was defective and unreasonably dangerous when it left the possession of Defendants in that VIOXX contained warnings which were misleading regarding the purported benefits associated with VIOXX and were inadequate and insufficient to alert physicians and consumers, such as Plaintiff, to the dangerous risks and reactions associated with VIOXX, including, but not limited to, cardiovascular risks, including myocardial infarction and other serious and life threatening side affects. Plaintiff's injuries and losses are continuing in nature.

50. The physicians prescribed VIOXX to Plaintiff for the intended purpose.

51. Neither the prescribing physicians nor Plaintiff could have discovered any defect in VIOXX through the exercise of reasonable care.

52. Defendants are held to the level of knowledge of an expert in the field.

53. The prescribing physicians did not have substantially the same knowledge as an adequate warning from the manufacturer, distributor or sales representative should have communicated to the prescribing physician.

54. The warnings that were given by Defendants to the prescribing physicians were not adequate, accurate, or clear, and were ambiguous.

55. Defendants had a continuing duty to warn the prescribing physicians and Plaintiff of the dangers associated with VIOXX.

56. As a direct and legal result of Defendants' failure to warn, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for damages, as well as all costs of this action.

**COUNT VI**
**FRAUDULENT/NEGLIGENT MISREPRESENTATION**

57. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

58. Defendants, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of VIOXX owed a duty to provide complete and accurate information regarding VIOXX to Plaintiff, her physicians, and anyone else Defendants knew or should have known would ingest or prescribe VIOXX.

59. Defendants misrepresented material facts regarding the safety and efficacy of VIOXX, and failed to inform Plaintiff, the public and Plaintiff's prescribing physician of these material facts.

60. Defendants fraudulently and/or negligently misrepresented to Plaintiff, Plaintiff's physicians, the FDA, and the general

public that VIOXX was safe and effective, that the benefits of taking VIOXX outweighed any risks, and/or fraudulently and/or negligently misrepresented and concealed safety and effectiveness information regarding the product, including but not limited to VIOXX's propensity to cause serious physical harm. The continuous and ongoing course of action constituting fraudulent and/or negligent misrepresentation on Plaintiff started at least as early as 2000, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

61. VIOXX was in fact unsafe and the use of VIOXX posed a risk of injury and death which outweighed the purported benefits of its use, such that injury was in fact caused to Plaintiff and others.

62. Defendants made fraudulent and/or negligent misrepresentations regarding adverse information at a time when it knew, or should have known, that VIOXX had defects, dangers, and characteristics that were other than what Defendants had represented to the prescribing

doctors or other dispensing entities, the FDA, and the consuming public, including Plaintiff. Specifically, Defendants misrepresented the following:

a. It was dangerous to prescribe VIOXX;
b. VIOXX carried risks of serious, life threatening adverse effects;

63. The misrepresentations alleged above were perpetuated directly and indirectly by the Defendants.

64. The fraudulent and/or negligent misrepresentations of Defendants took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information regarding the products while having a duty to disclose to Plaintiff and others such information.

65. Defendants knew or should have known that these representations were misleading at the time they were made or omitted, and made the representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely

on them, leading to the use of VIOXX by Plaintiff.

66. At the time of Defendants' fraudulent and/or negligent misrepresentations, Plaintiff and Plaintiff' physicians were unaware of the inaccuracy of the statements being made and believed them to be true.

67. Plaintiff's physician and Plaintiff justifiably relied on and were induced by the misrepresentations and relied on the absence of adverse safety information in the prescription and ingestion of VIOXX.

68. Defendants had a post-sale duty to warn Plaintiff and or Plaintiff's physicians about the potential risks and complications associated with VIOXX in a timely manner.

69. The misrepresentations by Defendants constitute a continuing tort.

70. Defendants made the statements and/or omissions with the intention that Plaintiff, Plaintiff's prescribing physicians or other dispensing entities and the consuming public would rely on such or the absence of such

information in selecting VIOXX as a treatment for arthritis and pain management.

71. As a direct and legal result of the fraudulent and/or negligent misrepresentations of Defendants, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages, plus interest and costs.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues.

WHEREFORE, the plaintiff prays:

1. The judgment enter against the defendants on all Counts of this Complaint;

# CIVIL ACTION COVER SHEET

DOCKET NO.(S) 04-4301

**Trial Court of Massachusetts**
**Superior Court Department**
County: MIDDLESEX

| PLAINTIFF(S) | DEFENDANT(S) |
|---|---|
| Vera Gropper | MERCK & CO., INC., et al. |
| ATTORNEY, FIRM, ADDRESS AND TELEPHONE<br>(617)720-1333<br>David Strouss, Esquire BBO #546253<br>Marilyn McGoldrick, Esquire BBO #561766<br>Allyson Hauck, Esquire, BBO #659547<br>THORNTON & NAUMES, LLP<br>100 Summer St., 30th Fl., Boston, MA 02110<br>Board of Bar Overseers number: listed above | ATTORNEY (if known) |

## Origin code and track designation

Place and x in one box only:

- [x] 1.F01 Original Complaint
- [ ] 2.F02 Removal to Sup.Ct. C.231, s.104 (Before trial) (F)
- [ ] 3.F03 Retransfer to Sup.Ct.C.231,s.102C(X)
- [ ] 4.F04 District Court Appeal c.231,s.97 & 104 (After trial) (X)
- [ ] 5.F05 Reactivated after rescript; relief from judgment/Order (Mass.R.Civ.P.60) (X)
- [ ] 6.E10 Summary Process Appeal (X)

**TYPE OF ACTION AND TRACK DESIGNATION (See Reverse Side)**

| CODE NO. | TYPE OF ACTION (specify) | TRACK | IS THIS A JURY CASE? |
|---|---|---|---|
| E99 | Consumer Protection under M.G.L. c. 93A and c. 176D | (A) | (X) Yes ( ) No |

**The following is a full, itemized and detailed statement of the facts on which plaintiff relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.**

**TORT CLAIMS**
(Attach additional sheets as necessary)

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
FOR THE COUNTY OF MIDDLESEX
OCT 29 2004
CLERK

| | |
|---|---|
| A. Documented medical expenses to date: | |
| 1. Total hospital expenses | $..see attached.. |
| 2. Total Doctor expenses | $..see attached.. |
| 3. Total chiropractic expenses | $..see attached.. |
| 4. Total physical therapy expenses | $..see attached.. |
| 5. Total other expenses (describe) | $..see attached.. |
| **Subtotal** | **$..see attached..** |
| B. Documented lost wages and compensation to date | $..see attached.. |
| C. Documented property damages to date | $..see attached.. |
| D. Reasonably anticipated future medical and hospital expenses | $..see attached.. |
| E. Reasonably anticipated lost wages | $..see attached.. |
| F. Other documented items of damages (describe) | $..see attached.. |

G. Brief description of plaintiff's injury, including nature and extent of injury (describe)
Plaintiff suffered injuries out of her use of Vioxx manufactured, sold, promoted and supplied by the Defendants. In light of the damages, Plaintiff believes there is a reasonable likelihood that recovery will be in excess of $25,000.

$..see attached..

**CONTRACT CLAIMS**
(Attach additional sheets as necessary)
Provide a detailed description of claim(s):

**TOTAL $.....**

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT- None

**"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods."**

Signature of Attorney of Record _____ DATE: 10/29/04
, Esq.

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
DEPT. OF THE TRIAL
COURT 04-4301

K

VERA GROPPER,
Plaintiff

vs.

MERCK & CO., INC.,
and John and Jane Does, as
Sales representatives for
MERCK & CO., INC.,
Defendants.

FIRST AMENDED
COMPLAINT

Now comes the plaintiff, by her attorneys, and files the following complaint:

1. Party Plaintiff

The Plaintiff, Vera Gropper, resides at 14 Hall Avenue, Somerville, Massachusetts, 02144, and at all relevant times herein, was a resident of the Commonwealth of Massachusetts.

2. Party Defendants

2A. The Defendant, Merck & Co., Inc., (hereinafter "Merck") is a corporation incorporated under the laws of the State of New Jersey, having a principal place of business in the State of New Jersey, and has conducted business in the Commonwealth of Massachusetts. At all relevant times, hereto, Merck was in the

business of promoting, marketing, and distributing the pharmaceutical VIOXX(Refecoxib).

2b. John and Jane Does are sales representatives for Merck promoting and distributing VIOXX to physicians within the Commonwealth of Massachusetts. Upon information and belief all or some of the John and Jane Doe Sales Representatives are individuals residing in the Commonwealth of Massachusetts.

As used in this Complaint, the term "defendant" shall include any party defendants identified in paragraphs 2a through 2b hereof, and their predecessors, which shall include, but is not limited to, any person, corporation, company or business entity: which formed part of any combination, consolidation, merger or reorganization from which any party defendant was created or was the surviving corporation; whose assets, stock, property, products or product line was acquired by any party defendant; whose patent rights, trademark rights, trade secrets of goodwill was acquired by any party defendant; or which was dominated or controlled by any party defendant to such an extent that said party defendant was the "alter ego" of said corporation.

**JURISDICTION**

3. The plaintiff's cause of action arises from the defendants' (1) transacting business in Massachusetts; (2) contracting to supply and/or sell goods in Massachusetts; (3) doing or causing

a tortuous act to be done in Massachusetts; and/or (4) causing the consequence of a tortuous act to occur within Massachusetts, and the defendants do, or solicit business, or engage in a persistent course of conduct or derive substantial revenue from the sale of goods in Massachusetts.

**FACTS**

4. At all relevant times herein, the defendants individually and/or in conjunction with other persons or entities for whose conduct they were legally responsible developed, created, manufactured, designed, tested, labeled, packaged, distributed, supplied, marketed, sold, advertised, and/or otherwise distributed in interstate trade and commerce the drug VIOXX.

5. On information and belief, the drugs were manufactured, distributed, and sold as medication to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, for the management of acute pain in adults, and the treatment of primary dysmenorrheal.

6. In May of 1999 VIOXX was approved by the FDA. The defendants individually began actively and aggressively promoting, marketing and selling the drug in the United States and eighty other countries. The defendants fraudulently induced people to use its drug for arthritis and pain relief without adequately warning people of the risks associated with the drug that were known or should have been known to the defendants.

7. The defendants engaged in a nationwide marketing scheme including but not limited to the Commonwealth of Massachusetts and participated in advertisements and promotional enhancements and literature, directly targeting consumers and various physicians and other health care providers.

8. The defendants, engaged in the study "VIOXX GATROINTESTINAL OUTCOMES RESEACH" ("VIGOR"). The results of the study were released in March 2000 and the findings demonstrated that VIOXX patients were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on Naprosyn (Naproxen).

9. On information and believe, MERCK mislead patients and health care providers by using press releases, promotional materials and oral representations made by MERCK and through MERCK's sales representatives, to offer an untested hypothetical explanation to assert that VIOXX did not cause an increase in MIs as demonstrated in the VIGOR study.

10. On September 17, 2001 a warning letter was sent by the Department of Health and Human Services, Food and Drug Administration (FDA), requiring MERCK to end all violative promotional materials and send "dear Healthcare provider" letters to communicate the accurate findings and risks of VIOXX demonstrated in the VIGOR study.

11. The Defendant MERCK did not communicate the findings of cardiovascular risks from the

VIGOR study until April 2002 when they sent a "Dear Doctor" letter and made changes and additions to VIOXX label regarding cardiovascular risks under the header "Precautions". MERK did not add stroke or any of the other adverse reactions linked to VIOXX that it knew or should have known.

12. The defendants engaged in and/or actively participated in inducing and/or encouraging use of VIOXX by providing incentives for its use and by encouraging physicians and other health care providers to prescribe it without the benefit of the full and complete information known to the defendants. The defendants disseminated false and misleading materials which failed to disclose the risks associated with the use of VIOXX.

13. Upon information and belief, the defendants also unfairly and deceptively encouraged the use of VIOXX, by falsely misleading potential users including the plaintiff, Vera Gropper, concerning the risks associated with its use. By affirmative misrepresentations and omission, the defendants sought to create the impression that VIOXX was safe for human use and constituted a safe form of a non-steroid anti-inflammatory drug.

14. The defendants failed to protect users from serious dangers that the defendants knew or should have known would result from the use of VIOXX.

15. The defendants failed to adequately disclose, warn, instruct and/or provide guidance to consumers concerning the health hazards and risks associated with the use of VIOXX, which were known or should have been known to the defendants.

16. The defendants engaged in the distribution and/or use of VIOXX without providing full and complete instructions and/or warnings.

17. The defendants failed to adequately and properly test and/or research the health effects of VIOXX.

18. The defendants engaged in this conduct knowing that VIOXX was being prescribed to people who were not aware of the serious cardiovascular risks of the drug.

19. The promotional campaign initiated, created, monitored, an/or supported by the defendants was intended to fraudulently induce and misrepresent in an affirmative manner the belief that through the use of VIOXX, arthritis and other pain could be managed with no serious or significant side effects or adverse reactions that would be experienced by the users of the drugs. This information was false, misleading, and fraudulent. At all times relevant herein, the defendants intentionally withheld and/or failed to adequately communicate known and/or potential health hazards and risks associated with the use of the drugs. The promotional campaign continued to create the false impression

of the successful and safe use of the drug, while at the same time the defendants were not communicating information regarding risks and complications that were known by or should have been known to the defendants.

20. The defendants fraudulently, deceptively, and unfairly misrepresented the facts regarding VIOXX, including but not limited to adequate testing of the drug and the efficiency, severity, frequency, and discomfort of side effects and adverse health effects caused by VIOXX.

21. As a result of the defendants' deceptive and unfair advertising and marketing practices, VIOXX was distributed throughout the United States and upon information and belief, over 1 million prescriptions for VIOXX were written in the United States, including Massachusetts, prior to the removal of VIOXX from the market.

22. The plaintiff began to consume VIOXX in August 2000 through approximately September 2004.

23. The plaintiff suffered a myocardial infarction while taking VIOXX.

24. On September 30, 2004, the defendant Merck announced a voluntary worldwide withdrawal of VIOXX from the market after the Adenomatous Polyp Prevention trial (APPROVe) confirmed the cardiovascular risks previously found in the VIGOR study.

**COUNT I**

**NEGLIGENCE**

25. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

26. It was the duty of the defendants to use and exercise reasonable and due care in the manufacture, development, design, formulation, testing, inspection, production, advertisement, promotion, marketing, sale and distribution of VIOXX.

27. It was also the duty of the defendant to provide detailed and adequate instructions relative to the proper and safe use of VIOXX and to provide detailed and adequate warnings concerning any and all dangers, characteristics, and potentialities of VIOXX, including known or suspected risks from the use of VIOXX, and to prevent a product which they knew or with reasonable care should have known was unreasonably dangerous and defective from entering the channels of trade.

28. It was the continuing duty of the defendants to advise and warn purchasers, consumer, users, medical providers and other health care providers of all dangers, characteristics, potentialities and defects discovered subsequent to their initial marketing or sale of VIOXX.

29. Yet, nevertheless, wholly disregarding the aforesaid duties, the defendants breached their duties by:

a. unreasonable, careless and negligent conduct in the design, development, formulation, manufacture, advertisement, promotion, marketing, sale, and distribution of VIOXX;

b. failing to adequately test VIOXX;

c. failing to warn or instruct, or adequately warn or adequately instruct, physicians and medical providers concerning the risk or likelihood of, inter alia, cardiovascular events in individuals who have consumed VIOXX and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

d. failing to warn or instruct, or adequately warn or adequately instruct the plaintiff and consumers of VIOXX concerning the risk or likelihood of, inter alia, suffering cardiovascular events and other medical complications associated with the use of VIOXX which defendants had or should have had knowledge of;

e. by placing in the channels of trade a drug which defendants knew or with reasonable care should have known was unreasonably dangerous and unsafe and by placing VIOXX in the channel of trade in a manner which the defendants foresaw, or in the exercise of reasonable care ought to have foreseen, would carry VIOXX into contact with persons such as the plaintiff, and by failing to use reasonable care to prevent injury to such persons, including the plaintiff.

f. marketing an inherently unsafe and/or dangerous drug;

g. misrepresenting that VIOXX was safe when the defendants knew, or in the exercise of reasonable care should have known, that VIOXX was dangerous and unsafe.

h. failing to provide adequate field and clinical testing both before and after marketing VIOXX;

i. failing to disclose known risks and instead minimizing the risks associated with the use of VIOXX in promotional campaigns and materials and oral representations.

j. failing to adequately warn of reactions, side effect, and complications associated with the use of VIOXX.

30. As a direct and proximate result of the unreasonable, careless, and negligent conduct of the defendants, the plaintiff, Vera Gropper, was caused to sustain severe and permanent injuries including a Myocardial Infarction, as a result of which the plaintiff has incurred medical expenses, incurred mental and physical pain and suffering, and suffered an impairment in her enjoyment of life, which damages are continuing in nature.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT II**

**BREACH OF EXPRESSED AND IMPLIED WARRANTIES**

31. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

32. The plaintiff was a person whom the defendants could reasonably have expected to use, consume, or be affected by the defendants' products within the meaning of Massachusetts General Laws c. 106, §2-318, as the defendants knew or had reason to know that their products could cause serious cardiovascular injuries.

33. The defendants expressly and impliedly warranted that VIOXX was safe, merchantable, fit for consumption, and for the use for which it was intended and fit for its particular purpose to relieve the signs and symptoms of osteoarthritis and rheumatoid arthritis, the management of acute pain in adults, and the treatment of primary dysmenorrheal.

34. The defendants knew or had reason to know of the particular purposes for which VIOXX would be used.

35. The plaintiff relied upon the defendants' skill or judgment to furnish or select a suitable product.

36. The defendants breached said warranties to the plaintiff because VIOXX was unsafe and not of merchantable quality.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages, plus interests and costs.

**COUNT III**

**MALICIOUS, WILLFUL, WANTON, AND RECKLESS CONDUCT OR GROSS NEGLIGENCE**

37. The plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

38. At least by 2000, the defendants, or some of them, possessed medical and scientific data indicating that VIOXX posed potentially serious cardiovascular risks and as early as this date the defendants, or some of them, possessed medical and scientific data indicating that the use of VIOXX was potentially hazardous to the health and safety of Vera Gropper and others in her position.

39. Prompted by pecuniary motives, the defendants ignored and failed to act upon such medical and scientific data and deprived the public, and particularly the users, from access to said medical and scientific data, thereby depriving them of informed and free choice as to whether or not to consume VIOXX.

40. The defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, by continuing to market VIOXX with reckless disregard for the health and safety of the plaintiff an others users and consumers, knowing the dangerous characteristics and propensities of VIOXX, but still depriving those

affected by the dangers from information about those dangers.

41. Because the defendants acted maliciously, willfully, wantonly, recklessly, or with gross negligence, in marketing their hazardous product, in ignoring the medical and scientific data which was available to them, and depriving consumers, users, and the general public from that medical and scientific data, the plaintiff is entitled to compensatory damages.

WHEREFORE, the plaintiff, Vera Gropper, demands compensatory damages plus interest and costs.

**COUNT IV**

**DEFECTIVE DESIGN/STRICT LIABILITY**

42. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

43. At all times material hereto, Defendants engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling VIOXX that were defective and unreasonably dangerous to consumers, including Plaintiff.

44. At all times material hereto, VIOXX which were researched, formulated, tested,

developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold by Defendants were expected to reach, and did reach, prescribing physicians and consumers including Plaintiff, without substantial change in the condition in which they were sold.

45. At all times material hereto, VIOXX was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

A. When placed in the stream of commerce, VIOXX contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks which exceeded the benefits of VIOXX;
B. When placed in the stream of commerce, VIOXX were defective in design and formulation, making use of VIOXX more dangerous than an ordinary consumer would expect;
C. VIOXX were insufficiently tested;
D. The intended use of VIOXX caused harmful side effects which outweighed any potential utility; and
E. VIOXX were not safe for its intended use as a weight loss drug.

46. But for the aforementioned defective and unreasonably dangerous conditions, VIOXX would not have been prescribed to Plaintiff, Plaintiff would not have ingested VIOXX, and Plaintiff would not have sustained the injuries alleged herein.

47. As a direct and legal result of the defective condition of VIOXX, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and/or nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages plus interest and costs.

**COUNT V**
**FAILURE TO WARN/STRICT LIABILITY**

48. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

48. VIOXX was defective and unreasonably dangerous when it left the possession of Defendants in that VIOXX contained warnings which were misleading regarding the purported benefits associated with VIOXX and were inadequate and insufficient to alert physicians and consumers, such as Plaintiff, to the dangerous risks and reactions associated with VIOXX, including, but not limited to, cardiovascular risks, including myocardial infarction and other serious and life threatening side affects. Plaintiff's injuries and losses are continuing in nature.

50. The physicians prescribed VIOXX to Plaintiff for the intended purpose.

51. Neither the prescribing physicians nor Plaintiff could have discovered any defect in VIOXX through the exercise of reasonable care.

52. Defendants are held to the level of knowledge of an expert in the field.

53. The prescribing physicians did not have substantially the same knowledge as an adequate warning from the manufacturer, distributor or sales representative should have communicated to the prescribing physician.

54. The warnings that were given by Defendants to the prescribing physicians were not adequate, accurate, or clear, and were ambiguous.

55. Defendants had a continuing duty to warn the prescribing physicians and Plaintiff of the dangers associated with VIOXX.

56. As a direct and legal result of Defendants' failure to warn, Plaintiff have sustained serious and permanent injuries including, but not limited to, injuries to the heart, strokes and/or other physical injuries, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff' injuries and losses are continuing in nature.

WHEREFORE, Plaintiff demand judgment against Defendants for damages, as well as all costs of this action.

**COUNT VI**
**FRAUDULENT/NEGLIGENT MISREPRESENTATION**

57. Plaintiff adopts by reference all of the allegations above, each inclusive, as though fully set forth herein.

58. Defendants, having undertaken the manufacturing, marketing, prescription dispensing, distributing and promotion of VIOXX owed a duty to provide complete and accurate information regarding VIOXX to Plaintiff, her physicians, and anyone else Defendants knew or should have known would ingest or prescribe VIOXX.

59. Defendants misrepresented material facts regarding the safety and efficacy of VIOXX, and failed to inform Plaintiff, the public and Plaintiff's prescribing physician of these material facts.

60. Defendants fraudulently and/or negligently misrepresented to Plaintiff, Plaintiff's physicians, the FDA, and the general

public that VIOXX was safe and effective, that the benefits of taking VIOXX outweighed any risks, and/or fraudulently and/or negligently misrepresented and concealed safety and effectiveness information regarding the product, including but not limited to VIOXX's propensity to cause serious physical harm. The continuous and ongoing course of action constituting fraudulent and/or negligent misrepresentation on Plaintiff started at least as early as 2000, if not earlier, and continued through repeated acts and non-disclosure every year since then throughout the United States and elsewhere.

61. VIOXX was in fact unsafe and the use of VIOXX posed a risk of injury and death which outweighed the purported benefits of its use, such that injury was in fact caused to Plaintiff and others.

62. Defendants made fraudulent and/or negligent misrepresentations regarding adverse information at a time when it knew, or should have known, that VIOXX had defects, dangers, and characteristics that were other than what Defendants had represented to the prescribing

doctors or other dispensing entities, the FDA, and the consuming public, including Plaintiff. Specifically, Defendants misrepresented the following:

a. It was dangerous to prescribe VIOXX;
b. VIOXX carried risks of serious, life threatening adverse effects;

63. The misrepresentations alleged above were perpetuated directly and indirectly by the Defendants.

64. The fraudulent and/or negligent misrepresentations of Defendants took the form of, among other things, express and implied statements, publicly disseminated misinformation, misinformation provided to regulatory agencies, inadequate, incomplete and misleading warnings about the subject products, failure to disclose important safety and injury information regarding the products while having a duty to disclose to Plaintiff and others such information.

65. Defendants knew or should have known that these representations were misleading at the time they were made or omitted, and made the representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely

on them, leading to the use of VIOXX by Plaintiff.

66. At the time of Defendants' fraudulent and/or negligent misrepresentations, Plaintiff and Plaintiff' physicians were unaware of the inaccuracy of the statements being made and believed them to be true.

67. Plaintiff's physician and Plaintiff justifiably relied on and were induced by the misrepresentations and relied on the absence of adverse safety information in the prescription and ingestion of VIOXX.

68. Defendants had a post-sale duty to warn Plaintiff and or Plaintiff's physicians about the potential risks and complications associated with VIOXX in a timely manner.

69. The misrepresentations by Defendants constitute a continuing tort.

70. Defendants made the statements and/or omissions with the intention that Plaintiff, Plaintiff's prescribing physicians or other dispensing entities and the consuming public would rely on such or the absence of such

WHEREFORE, Plaintiff demand judgment against Defendants for compensatory damages, plus interest and costs.

**Count VII**

**Violation of M.G.L. c.93A**

72. The plaintiff repeats, realleges, and reavers paragraphs one through seventy-one above as if expressly set forth fully hereinafter.

73. At all relevant times hereto the defendants were engaged in trade or commerce.

74. The acts of the defendants alleged in Counts I through VI, and as outlined in the Facts, constitute unfair or deceptive acts or practices within the meaning of G.L. c. 93A, §§ 2 and 3, 940 C.M.R. 3.05(1), and 940 C.M.R. 3.16(1) and (2).

75. The actions of the defendants described herein were performed willfully and knowingly.

76. As a result of the unfair or deceptive acts or practices described in the Facts, the plaintiff sustained injury including but not limited to the injuries stated in Paragraph 23 above, incorporated herein.

Wherefore, the plaintiff, Vera Gropper demands judgment against the defendants in an amount that is

fair and reasonable; plus treble such amount as provided by M.G.L. c. 93A, sec. 9(3); plus interest, costs and attorneys' fees to the plaintiff; and award such other relief as this Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all issues.

WHEREFORE, the plaintiff prays:

1. The judgment enter against the defendants on all Counts of this Complaint;
2. That plaintiff be awarded full, fair and complete compensation, for which she is legally entitled;
3. That the plaintiff be awarded full, fair, and complete compensation plus treble amount, attorney's fees and costs under M.G.L. c. 93A, §§ 2 and 9;
4. that plaintiff be awarded all appropriate costs, attorney's fees and interest authorized by law;
5. That the court enter such other relief as is determined just and appropriate.

Respectfully Submitted,

David C. Strouss (BBO#546253)
Marilyn T. McGoldrick, (BBO#561766)
Allyson S. Hauck (BBO#659547)
THORNTON & NAUMES, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
(617)720-1333

Dated: January 5, 2005

COMMONWEALTH OF MASSACHUSETTS

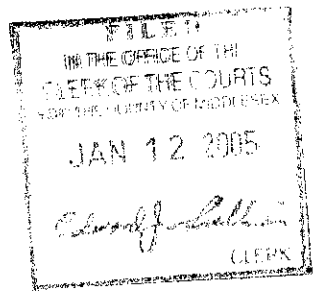
MIDDLESEX, ss.

SUPERIOR COURT
DEPT. OF THE TRIAL
COURT 04-4301

VERA GROPPER,
Plaintiff

vs.

MERCK & CO., INC.,
and John and Jane Does, as
Sales representatives for
MERCK & CO., INC.,
Defendants.




NOTICE OF ADDITION OF VIOLATION OF M.G.L. c.93A
COUNT AND FILING OF FIRST AMENDED COMPLAINT

Now come the plaintiff, pursuant to Mass. R. Civ. P. 15(a) and files the attached First Amended Complaint in regard to the above-captioned matter.

The First Amended Complaint reflects the addition of a count for violation of the Consumer Protection Act, M.G.L. c. 93A against all defendants. In support

of this notice, plaintiff's counsel states that no responsive pleading has been served.

Respectfully submitted,

David C. Strouss, BBO#546253
Marilyn T. McGoldrick, BBO#561766
Allyson S. Hauck, BBO# 659547
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
(617) 720-1333

DATED: 1/12/05

CERTIFICATE OF SERVICE

I, Allyson S. Hauck, Esquire, hereby certify that on this day I mailed, postage prepaid, a copy of the foregoing Notice of Addition of M.G.L. c.93A Count and Filing of First Amended Complaint to all defendants' counsel of records in the above-captioned matter.

DATED: 1/12/05

**Commonwealth of Massachusetts**
**MIDDLESEX SUPERIOR COURT**
**Case Summary**
**Civil Docket**



# MICV2004-04301
# Gropper v Merck & Co., Inc. et al

| | | | |
|---|---|---|---|
| **File Date** | 10/29/2004 | **Status** | Disposed: transfered to other court (dtrans) |
| **Status Date** | 02/10/2005 | **Session** | K - Cv K (9A Cambridge) |
| **Origin** | 1 | **Case Type** | E99 - Miscellaneous |
| **Lead Case** | | **Track** | X |

| | | | | | |
|---|---|---|---|---|---|
| **Service** | 01/27/2005 | **Answer** | 03/28/2005 | **Rule12/19/20** | |
| **Rule 15** | | **Discovery** | | **Rule 56** | |
| **Final PTC** | 04/27/2005 | **Disposition** | 05/27/2005 | **Jury Trial** | Yes |

**Plaintiff**
Vera Gropper
14 Hall Avenue
Somerville, MA 02144
Active 10/29/2004

**Private Counsel 546253**
David C Strouss
Thornton & Naumes
100 Summer Street
30th floor
Boston, MA 02110
Phone: 617-720-1333
Fax: 617-720-2445
Active 10/29/2004 Notify

**Private Counsel 561766**
Marilyn T McGoldrick
Thornton & Naumes
100 Summer Street
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Boston, MA 02110
Phone: 617-720-1333
Fax: 617-720-2445
Active 10/29/2004 Notify

**Private Counsel 659547**
Allyson Hauck
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30th floor
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Phone: 617-720-1333
Fax: 617-720-2445
Active 10/29/2004 Notify

**Defendant**
Merck & Co., Inc.
Served: 01/14/2005
Answered: 02/03/2005
Answered 02/03/2005

**Private Counsel 651516**
Bradley E. Abruzzi
Foley Hoag LLP
155 Seaport Boulevard
19th floor
Boston, MA 02110
Phone: 617-832-1000
Fax: 617-832-7000
Active 02/03/2005 Notify

**Commonwealth of Massachusetts**
**MIDDLESEX SUPERIOR COURT**
**Case Summary**
**Civil Docket**

# MICV2004-04301
# Gropper v Merck & Co., Inc. et al

| | |
|---|---|
| | **Private Counsel 124660**<br>James J Dillon<br>Goodwin Procter<br>53 State Street<br>Exchange Place<br>Boston, MA 02109<br>Phone: 617-570-1000<br>Fax: 617-523-1231<br>Active 02/10/2005 Notify |
| **Defendant**<br>John Doe<br>Sales Rep. for Merck & Co., Inc.<br>Service pending 10/29/2004 | |
| **Defendant**<br>Jane Doe<br>Sales Rep. for Merck & Co., Inc.<br>Service pending 10/29/2004 | |

| Date | Paper | Text |
|---|---|---|
| 10/29/2004 | 1.0 | Complaint & civil action cover sheet filed |
| 10/29/2004 | | Origin 1, Type E99, Track X. |
| 01/12/2005 | 2.0 | Plff's Amended complaint reflects the addition of a Count for violation of the Consumer Protection Acts, MGL c.93 against all defts |
| 01/14/2005 | 3.0 | Plff's Motion to appoint Timothy McGonigal, D H R and Associates or any associate as Special Process Server. Filed in Court and Allowed. (White, J.) |
| 01/20/2005 | 4.0 | SERVICE RETURNED (amended complaint): Merck & Co., Inc.(Defendant) 01/4/05 in hd, 101 Federal St., Boston, MA |
| 02/03/2005 | 5.0 | ANSWER: Merck & Co., Inc.(Defendant) |
| 02/10/2005 | 6.0 | Case REMOVED this date to United States District Court of Massachusetts by Defendant Merck & Co., Inc. |
| 02/10/2005 | | ABOVE ACTION THIS DAY REMOVED TO UNITED STATES DISTRICT COURT. |

COMMONWEALTH OF MASSACHUSETTS
TRIAL COURT

Middlesex SS.

3

Superior Court
Docket #04-4301

Vera Gropper
Plaintiff(S)

Vs.

Merck & Co., Inc., et al.
Defendant(S)

MOTION FOR APPOINTMENT AS PROCESS SERVER

In accordance with the provisions of Rule 4(c) of the Massachusetts Rules of Civil Procedure, the undersigned hereby moves this Court for the appointment of **Timothy McGonigal, D H R and Associates** or any associate as process server in the above-entitled case. The undersigned swears that to the best of his/her knowledge and belief that the person to be appointed process server is a Constable who is experienced in the service of process, is 18 years of age or over and is not a party to this action.

By: David C Strouss
BBO# 546253
David C. Strouss, Esquire
100 Summer Street, 30th Floor
Boston, MA 02110

Middlesex SS. Superior Court

Allowed by the Court:
(White J.)

Attest: Patricia A. McCann
Deputy Asst Clerk
Dated: Jan 14, 2005

D H R and Associates
Constables
357 Cambridge Street
Cambridge, MA 02141
(617) 868-6733
FAX: (617) 868-0334

2005 January 14 (White, J.)
Filed in Court and
allowed
attest: Patricia A. McCann
Deputy Asst. Clerk

**TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED: — TORT — MOTOR VEHICLE TORT -- CONTRACT — EQUITABLE RELIEF — OTHER**

## COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX , ss
{seal}

SUPERIOR COURT
DEPARTMENT
OF THE
TRIAL COURT
CIVIL ACTION
No. 04-4301

Vera Gropper , Plaintiff(s)

v.

Merck & Co., Inc. and John and Jane Does, as Sales Representatives for Merck & Co., Inc. , Defendant(s)

CLERK FOR THE COURT
JAN 20 2005
Edward J. Sullivan
CLERK

## SUMMONS

To the above-named Defendant: Merck & Co., CT corporation, 101 Federal Street, Boston, MA

You are hereby summoned and required to serve upon David C. Strouss, Esquire, Thornton & Naumes, LLP plaintiff's attorney, whose address is 100 Summer Street, 30th Floor Boston, MA 02110 an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Cambridge, MA either before service upon plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

Witness, Suzanne V. DelVecchio [redacted] Esquire, at

the 12th day of January , in the year of our Lord 2004 .

Edward J. Sullivan
Clerk

NOTES.
1. This summons is issued pursuant to Rule 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all such defendants should appear in the caption. If a separate summons is used for each defendant, each should be addressed to the particular defendant.

FORM NO. SUP. — 001

5

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS.

SUPERIOR COURT
DEPT. OF THE
TRIAL COURT

VERA GROPPER,

Plaintiff,

v.

MERCK & CO., INC., and John and Jane Does, as Sales Representatives for MERCK & CO, INC.,

Defendants.

CIVIL ACTION No. 04-4301

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
FOR THE COUNTY OF MIDDLESEX
FEB 3 2005
CLERK

**ANSWER TO FIRST AMENDED COMPLAINT**

Defendant Merck & Co., Inc. ("Merck") states the following, in answer to the numbered allegations set forth in the First Amended Complaint of Vera Gropper:

1. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint.

2. Defendant Merck denies each and every allegation in Paragraph 2a of the Complaint except admits that Merck is a New Jersey corporation with its principal place of business in the State of New Jersey, that Merck manufactured, marketed, and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004, and that VIOXX® is Merck's trade name for rofecoxib. The allegations contained in Paragraph 2b of the Complaint are not directed at Merck, and therefore no responsive pleading is required.

Defendant Merck denies the definition of "Defendants" that follows Paragraph 2b and will respond to the allegations in the Complaint solely as to the corporate entity Merck.

JURISDICTION

3. Defendant Merck denies each and every allegation contained in Paragraph 3 of the Complaint.

FACTS

4. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 4 of the Complaint and denies each and every allegation directed toward Merck in said paragraph, except admits that Merck manufactured, marketed and distributed the prescription medicine VIOXX® until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

5. Defendant Merck denies each and every allegation contained in Paragraph 5 of the Complaint and avers that Merck sought and received the approval of the FDA to manufacture and market the prescription medicine VIOXX® and, until the voluntary withdrawal of VIOXX® on September 30, 2004, did market VIOXX® for the indicated uses set out in the relevant FDA approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

6. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 6 of the Complaint, denies each and every allegation directed toward Merck in Paragraph 6 of the Complaint and avers that Merck sought and received the approval of the FDA to manufacture and market the prescription medicine VIOXX® and, until the voluntary withdrawal of VIOXX® on September 30, 2004, did market VIOXX® for the indicated uses set out in the relevant FDA approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

7. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 7 of the Complaint, and denies each and every allegation directed toward Merck in Paragraph 7 of the Complaint except admits that, until Merck announced the voluntary withdrawal of VIOXX® on September 30, 2004, it marketed the prescription medicine VIOXX®, which was approved by the FDA as safe and effective for certain indicated uses subject to the information in the FDA-approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

8. Defendant Merck denies each and every allegation contained in Paragraph 8 of the Complaint, except admits that the referenced study exists, and respectfully refers the Court to the referenced study for its actual conclusions and full text.

9. Defendant Merck denies each and every allegation in Paragraph 9 of the Complaint.

10. Defendant Merck denies each and every allegation in Paragraph 10 of the complaint except admits that Merck received a letter from a regulatory review officer in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

11. Defendant Merck denies each and every allegation in Paragraph 11 of the Complaint except admits that in April 2002 the FDA approved certain changes to the VIOXX® prescribing information and respectfully refers the Court to the prescribing information for VIOXX® for its actual language and full text.

12. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 12 of the Complaint

and denies each and every allegation directed toward Merck in Paragraph 12 of the Complaint except admits that, until Merck announced the voluntary withdrawal of VIOXX® on September 30, 2004, it marketed the prescription medicine VIOXX®, which was approved by the FDA as safe and effective for certain indicated uses subject to the information in the FDA-approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

13. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 13 of the Complaint and denies each and every allegation directed toward Merck in Paragraph 13 of the Complaint except admits that, until Merck announced the voluntary withdrawal of VIOXX® on September 30, 2004, it marketed the prescription medicine VIOXX®, which was approved by the FDA as safe and effective for certain indicated uses subject to the information in the FDA-approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

14. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 14 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 14 of the Complaint.

15. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 15 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 15 of the Complaint.

16. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 16 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 16 of the Complaint.

17. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 17 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 17 of the Complaint.

18. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 18 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 18 of the Complaint.

19. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 19 of the Complaint and denies each and every allegation directed toward Merck in Paragraph 19 of the Complaint except admits that, until Merck announced the voluntary withdrawal of VIOXX® on September 30, 2004, it marketed the prescription medicine VIOXX®, which was approved by the FDA as safe and effective for certain indicated uses subject to the information in the FDA-approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

20. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 20 of the Complaint and denies each and every allegation directed toward Merck in Paragraph 20 of the Complaint

except admits that, until Merck announced the voluntary withdrawal of VIOXX® on September 30, 2004, it marketed the prescription medicine VIOXX®, which was approved by the FDA as safe and effective for certain indicated uses subject to the information in the FDA-approved prescribing information, and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

21. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 21 of the Complaint and denies each and every allegation in directed toward Merck in Paragraph 21 of the Complaint except admits that VIOXX® was prescribed to millions of patients by health care providers.

22. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 22 of the Complaint and in the alternative denies each and every allegation contained in said paragraph.

23. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 23 of the Complaint and in the alternative denies each and every allegation contained in said paragraph.

24. Defendant Merck denies each and every allegation contained in Paragraph 24 of the Complaint except admits that on September 30, 2004 Merck announced the voluntary worldwide withdrawal of VIOXX® and respectfully refers to the referenced announcement for its actual language and full text. Merck further avers that it announced on September 30, 2004 that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking VIOXX® compared with those taking placebo and that, given the availability of

alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of VIOXX® best served the interests of patients.

COUNT I: NEGLIGENCE

25. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 24 of the Complaint.

26. The allegations of Paragraph 26 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 26 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 26 of the Complaint, and respectfully refers the Court to the relevant state legal standard, including any conflict of laws rules.

27. The allegations of Paragraph 27 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 27 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 27 of the Complaint, and respectfully refers the Court to the relevant state legal standard, including any conflict of laws rules.

28. The allegations of Paragraph 28 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 28 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 28 of the Complaint, and respectfully refers the Court to the relevant state legal standard, including any conflict of laws rules.

29. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 29 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 29 of the Complaint, including subparts a-j.

30. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 30 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 30 of the Complaint.

COUNT II: BREACH OF EXPRESS AND IMPLIED WARRANTIES

31. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 30 of the Complaint.

32. The allegations of Paragraph 32 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 32 of the Complaint and in the alternative denies each and every allegation contained in said paragraph.

33. The allegations of Paragraph 33 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 33 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 33 of the Complaint.

34. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 34 of the

Complaint. Defendant Merck denies each and every allegation directed toward Merck contained in Paragraph 34 of the Complaint except admits that the FDA approved VIOXX® for certain indicated uses subject to the information contained in the FDA-approved prescribing information for VIOXX® and respectfully refers to the relevant prescribing information for VIOXX®'s indicated uses.

35. The allegations of Paragraph 35 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 35 of the Complaint and in the alternative denies each and every allegation contained in said paragraph.

36. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 36 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 36 of the Complaint.

COUNT III: MALICIOUS, WANTON,
AND RECKLESS CONDUCT OF GROSS NEGLIGENCE

37. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 36 of the Complaint.

38. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 38 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 38 of the Complaint.

39. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 39 of the Complaint

and denies each and every allegation directed toward Merck contained in Paragraph 39 of the Complaint.

40. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 40 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 40 of the Complaint.

41. The allegations of Paragraph 41 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 41 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 41 of the Complaint.

COUNT IV: DEFECTIVE DESIGN/STRICT LIABILITY

42. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 41 of the Complaint.

43. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 43 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 43 of the Complaint.

44. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 44 of the Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine VIOXX®, until Merck voluntarily withdrew VIOXX® from the market on September 30, 2004.

45. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 45 of the Complaint, and denies each and every allegation directed toward Merck contained in Paragraph 45 of the Complaint, including subparts A-E.

46. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 46 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 46 of the Complaint.

47. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 47 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 47 of the Complaint.

COUNT V: FAILURE TO
WARN/STRICT LIABILITY

48. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 48 of the Complaint.

49. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 49 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 49 of the Complaint, except admits that the FDA approved VIOXX® for certain indicated uses subject to the information contained in the FDA-approved prescribing information for VIOXX® and respectfully refers to the relevant prescribing information for its actual language and full text.

50. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 50 of the Complaint and in the alternative denies each and every allegation contained in said paragraph.

51. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 51 of the Complaint and in the alternative denies each and every allegation contained in said paragraph.

52. The allegations of Paragraph 52 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 52 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 52 of the Complaint.

53. Defendant Merck denies each and every allegation contained in Paragraph 53 of the Complaint, avers that the FDA approved VIOXX® for certain indicated uses subject to the information contained in the FDA-approved prescribing information for VIOXX® and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

54. Defendant Merck denies each and every allegation contained in Paragraph 54 of the Complaint, avers that the FDA approved VIOXX® for certain indicated uses subject to the information contained in the FDA-approved prescribing information for VIOXX® and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

55. The allegations of Paragraph 55 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant

Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 55 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 55 of the Complaint, and respectfully refers the Court to the relevant state legal standard, including any conflict of laws rules.

56. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 56 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 56 of the Complaint.

COUNT VI: FRAUDULENT/
NEGLIGENT MISREPRESENTATION

57. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 57 of the Complaint.

58. The allegations of Paragraph 58 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 58 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 58 of the Complaint, and respectfully refers the Court to the relevant state legal standard, including any applicable conflict of laws rules.

59. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 59 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 59 of the Complaint.

60. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 60 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 60 of the Complaint.

61. Defendant Merck denies each and every allegation contained in Paragraph 61 of the Complaint.

62. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 62 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 62 of the Complaint, and avers that the FDA approved VIOXX® for certain indicated uses subject to the information contained in the FDA-approved prescribing information for VIOXX® and respectfully refers to the relevant prescribing information for its actual language and full text.

63. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 63 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 63 of the Complaint.

64. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 64 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 64 of the Complaint, and avers that the FDA approved VIOXX® for certain indicated uses subject to the information contained in the FDA-approved prescribing information for VIOXX® and respectfully refers to the relevant prescribing information for its actual language and full text.

65. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 65 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 65 of the Complaint.

66. Defendant Merck denies each and every allegation contained in Paragraph 66 of the Complaint.

67. Defendant Merck denies each and every allegation contained in Paragraph 67 of the Complaint.

68. The allegations of Paragraph 68 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 68 of the Complaint, denies each and every allegation directed toward Merck contained in Paragraph 68 of the Complaint, and respectfully refers the Court to the relevant state legal standard, including any conflict of laws rules.

69. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 69 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 69 of the Complaint.

70. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 70 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 70 of the Complaint.

71. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 71 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 71 of the Complaint.

COUNT VII: VIOLATION
OF CHAPTER 93A

72. Defendant Merck hereby incorporates by reference the preceding specific responses to the allegations in Paragraphs 1 through 71 of the Complaint.

73. The allegations of Paragraph 73 of the Complaint are legal conclusions as to which no responsive pleading is required. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 73 of the Complaint and admits the allegations directed toward Merck contained in Paragraph 73 of the Complaint.

74. The allegations of Paragraph 74 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 74 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 74 of the Complaint.

75. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 75 of the Complaint and denies each and every allegation directed toward Merck contained in Paragraph 75 of the Complaint.

76. Defendant Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in Paragraph 76 of the Complaint

and denies each and every allegation directed toward Merck contained in Paragraph 76 of the Complaint.

## JURY DEMAND

Merck hereby requests a trial by jury.

## DEFENSES

### FIRST DEFENSE

The Complaint fails to set forth a cause of action upon which relief can be granted.

### SECOND DEFENSE

Any product for which Defendant Merck was responsible at the time of the occurrence or injuries alleged by the Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product or products at issue at the time of the occurrence or injuries alleged by the Plaintiff were legally adequate warnings and instructions.

### THIRD DEFENSE

The occurrence and injuries alleged by the Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of the Plaintiff and/or third parties over whom Merck had no control and for whom Merck is not responsible.

### FOURTH DEFENSE

If the Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons having no real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**FIFTH DEFENSE**

The occurrence and injuries alleged by the Plaintiff resulted from an intervening cause or a new and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrence and injuries alleged by the Plaintiff. Moreover, the occurrence and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any breach of legal duty on the part of Merck and the occurrence and injuries alleged by the Plaintiff, and thereby become the immediate and/or sole cause, and/or sole proximate and/or sole producing cause of such occurrence and injuries, relieving Merck of liability to the Plaintiff or any other parties.

**SIXTH DEFENSE**

If the Plaintiff sustained the injuries or incurred the expenses alleged, the same were caused, in whole or in part, by operation of nature or an act of God.

**SEVENTH DEFENSE**

If the Plaintiff sustained the injuries or incurred the expenses alleged, the same were caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of Merck.

**EIGHTH DEFENSE**

The injuries and damages alleged in the Plaintiff's Complaint were the result of unavoidable circumstances that could not have been prevented by anyone, including Merck.

**NINTH DEFENSE**

Any and all damages alleged by the Plaintiff were caused by misuse of the product or products at issue in this case, failure to use the product or products properly, and/or alteration or

negligent use of the product or products.

**TENTH DEFENSE**

The Plaintiff cannot recover under the Complaint because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**ELEVENTH DEFENSE**

The Plaintiff' claims are barred by the Plaintiff's contributory negligence and the contributory negligence of others.

**TWELFTH DEFENSE**

The Plaintiff's claims are barred by the Plaintiff's express and/or implied assumption of the risks, if any, inherent in the alleged use of the product or products at issue.

**THIRTEENTH DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrine of laches.

**FOURTEENTH DEFENSE**

The benefits of the product or products at issue outweigh the risks, if any, which may be attendant to their use.

**FIFTEENTH DEFENSE**

The damages and injuries alleged, if any, were caused or enhanced by a preexisting medical condition of the Plaintiff that was not related to any product manufactured by Merck.

**SIXTEENTH DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrine set forth in Comment k of the Restatement (Second) of Torts § 402A as to the product or products at issue.

**SEVENTEENTH DEFENSE**

The Plaintiff's claims are barred in whole or in part pursuant to comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**EIGHTEENTH DEFENSE**

The Plaintiff's claims are barred in whole or in part pursuant to comment j to Section 402A of the Restatement (Second) of Torts.

**NINETEENTH DEFENSE**

The Plaintiff's claims are barred under Section 4, et seq., of the Restatement (Third), of Torts: Product Liability.

**TWENTIETH DEFENSE**

Any warnings that Merck gave were transmitted to the prescribing physicians and/or health care providers and under Massachusetts law, Merck's only obligation is to warn the prescribing physician and/or health care providers and said obligation was fulfilled.

**TWENTY-FIRST DEFENSE**

Merck has complied with all requirements of the Food and Drug Administration of the United States Department of Health and Human Services, and the product or products at issue were approved pursuant to the applicable statutes and regulations. Pursuant to such, the product or products at issue could only be used pursuant to the prescription of a licensed prescriber. The package insert for the product or products at issue was also approved by the Food and Drug Administration, and the marketing was conducted in conformity with the regulations of the Food and Drug Administration. Therefore, the Plaintiff's claims are preempted.

**TWENTY-SECOND DEFENSE**

The Plaintiff's claims are barred by the applicable statute(s) of limitations.

**TWENTY-THIRD DEFENSE**

If the Plaintiff sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the negligence or fault of the Plaintiff and/or third parties, not from any negligence or breach of duty by Merck. Judgment may not enter for the Plaintiff if it is found that the Plaintiff was more negligent than Merck. If judgment is rendered in the Plaintiff's favor, the amount of such judgment must be reduced under the doctrine of comparative negligence.

**TWENTY-FOURTH DEFENSE**

Merck is unaware at this time of any settlement by any alleged joint tortfeasor. However, in the event any settlement is or has been made by any alleged joint tortfeasor, Merck is entitled to a credit/offset for such settlement.

**TWENTY-FIFTH DEFENSE**

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

**TWENTY-SIXTH DEFENSE**

The Plaintiff knew of the existence of the risks complained of in the Complaint, realized and appreciated the possibilities of injury as a result of the risk, and having had a reasonable opportunity to avoid it, voluntarily exposed herself to the risk.

**TWENTY-SEVENTH DEFENSE**

At the time the product at issue was manufactured, there was no practical and technically feasible alternative design or formulation that would have prevented the alleged harm without substantially impairing the usefulness of the product.

**TWENTY-EIGHTH DEFENSE**

Merck made no express or implied representations or warranties of any kind to the Plaintiff, nor did the Plaintiff rely on any representations or warranties made by Merck. To the extent the Plaintiff relied on any representations or warranties, such reliance was unjustified.

**TWENTY-NINTH DEFENSE**

Merck did not breach any duty of care to the Plaintiff.

**THIRTIETH DEFENSE**

The Plaintiff's claims are barred by the doctrine of estoppel.

**THIRTY-FIRST DEFENSE**

The Plaintiff's claims are barred by the doctrine of waiver.

**THIRTY-SECOND DEFENSE**

The Plaintiff has failed to join all necessary and indispensable parties.

**THIRTY-THIRD DEFENSE**

The Plaintiff's claims are barred because the Plaintiff has failed and refused to mitigate her alleged damages.

**THIRTY-FOURTH DEFENSE**

Merck did not violate any state or federal statute, regulation or ordinance to cause the Plaintiff' alleged injuries.

**THIRTY-FIFTH DEFENSE**

The Plaintiff's claims are barred in whole or in part due to a lack of notice.

**THIRTY-SIXTH DEFENSE**

To the extent that the Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by

federal law under the Supremacy Clause of the United States Constitution.

**THIRTY-SEVENTH DEFENSE**

The Plaintiff's claims are barred, in whole or in part, because the Plaintiff lacks capacity and/or standing to bring such claims.

**THIRTY-EIGHTH DEFENSE**

To the extent the Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**THIRTY-NINTH DEFENSE**

The Plaintiff's claims under Chapter 93A of the Massachusetts General Laws are barred because the Plaintiff did not provide Merck with written notice of her claim and because the conduct of Merck, selling a prescription drug approved by the FDA and accompanied by FDA-approved labeling and warnings, cannot constitute a violation of Chapter 93A.

**FORTIETH DEFENSE**

The Plaintiff's state-law claims are barred, in whole or in part, because VIOXX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FORTY-FIRST DEFENSE**

This case is more appropriately brought in a different venue.

**FORTY-SECOND DEFENSE**

The Complaint and the causes of action contained therein is barred in whole or in part by the United States and Massachusetts Constitutions, which prohibit the extraterritorial application of Massachusetts law.

**FORTY-THIRD DEFENSE**

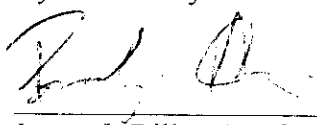
The Complaint and the causes of action contained therein is barred in whole or in part by the U.S. Constitution, article I, section VIII, clause 3 to the extent they seek to regulate Merck's practices outside of Massachusetts. That constitutional provision prohibits a State from regulating conduct that occurs wholly outside of its borders.

**FORTY-FOURTH DEFENSE**

Merck hereby gives notice that it intends to rely upon such other defenses as may become available or appear during discovery proceeding in this case and hereby reserves the right to amend its answer to assert any such defense.

**WHEREFORE**, Defendant Merck & Co. respectfully requests that the Plaintiff take nothing in this suit, that it recover its costs of court and expenses and such other relief to which it may show itself justly entitled.

MERCK & CO., INC.
By its attorneys:



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Bradley E. Abruzzi (BBO# 651516)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110-2600
(617) 832-1000

Dated: February 3, 2005

**CERTIFICATE OF SERVICE**

I certify that a true copy of the foregoing Answer was served on February 3, 2005 by hand, upon:

David C. Strouss
Thornton & Naumes, LLP
100 Summer Street, 30th Floor
Boston, MA 02110
**Counsel for Plaintiff Vera Gropper**